THE PERMISSIBILITY OF UTILISING STEM CELLS IN BIOMEDICAL TREATMENT IN ASEAN COUNTRIES: RELIGIOUS COMPLIANCE PERSPECTIVES

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ABSTRACT

With the rise of the halal market, more and more technologies are being used which are not specifically sanctioned by the Quran or the Sunnah. The use of stem cells in biomedical treatment, which has been claimed to have numerous beneficial effects on humans, was one of these subjects. Stem cell therapy represents a revolutionary development in medical science that offers a promising approach to treating various ailments. Hence, the present study was undertaken to (1) investigate the permissibility of employing stem cells following Islamic law, (2) ascertain the compatibility of stem cell utilisation with Islamic teachings, and (3) identify any limitations on its application. This research study is conducted using secondary library-based sources. It seeks to provide an overview of the ethical and legal considerations surrounding using stem cells as a biological treatment, specifically from the perspectives of chosen countries within ASEAN. The result shows that it is permissible to use stem cells as a treatment under strict conditions that serve to benefit mankind and that utilising them will not cause harm or invoke harm to the person or another person. It also aligns with *Maqasid Shari'ah*, which protects life and health and applies to several *Qawa'id Fiqhiyyah* (Legal Maxims). However, many challenges need to be considered regarding stem cell therapy, including ethical concerns. Therefore, several recommendations have been suggested to overcome the unethical issues of using stem cells for biomedical purposes.

Keywords: *ASEAN, Biomedical treatment, Religious Compliance, Stem Cells*

1. Introduction

In recent years, there has been a developing interest in halal due to the global growth of the Muslim population. The increase in interest in the halal market is restricted to ASEAN nations and extended to Middle Eastern nations such as the Western and Europe (Jaafar et al., 2013). Muslims spent the equivalent of US$2 trillion in 2021 in the food, pharmaceutical, cosmetics, fashion, travel, and media/recreation sectors, all influenced by the Islamic faith's emphasis on ethical consumption. By 2025, Muslim spending is anticipated to reach US$2,8 trillion (Dinar Standard, 2022).

Due to its positive perspective, the halal industry has seen significant growth and is presently acknowledged as one of the largest and most lucrative markets on a global scale. As a result of increased interest and demand, the halal industry has also witnessed the adoption and integration of various advancements and technology. There also exists an optimistic viewpoint about scientific study and the capacity of technology to facilitate progress, for instance, the domain of stem cell research and its capacity to sustain life for humans (Macer, n.d.).

Since the beginning, Islam has actively encouraged research in science, particularly that which aims to find medical cures for human illness (Fadel, 2012). Considering the various illnesses and ailments that individuals may experience, it is essential to acknowledge the profound compassion of Allah SWT, who has graciously provided pathways of hope through which individuals can seek remedies. That example can be observed in the hadith attributed to the esteemed Prophet Muhammad SAW:

"*Allah has not sent an illness without a cure*." (Sahih al-Bukhari)

"*Allah has sent down both the disease and the cure, and He has appointed a cure for every disease, so treat yourselves medically, but use nothing unlawful*." (Sunan Abu Daud)

Historically, conventional disease therapy primarily relied on administering pharmaceutical medications containing chemical compounds (Rizka & Budiwati, 2022). Currently, stem cells are a prominent area of interest in the field of biotechnology research, particularly in the context of cell therapy and regenerative medicine. Stem cell research has been the subject of heated debate in the fields of science, religious communities, and politics. It is argued that the potential to advance the treatment of numerous debilitating diseases and cancers with stem cells is contrasted with the moral principle of safeguarding human life from its earliest stages (Fadel, 2012).

Hence, the primary objective of this study was (1) to examine the Islamic legal perspective regarding the utilisation of stem cells in biomedical treatment, (2) to determine the permissibility of such usage within the framework of Islamic teachings, and (3) to explore any potential restrictions or limitations associated with these applications.

2. Literature Review

According to Rizka and Budiwati (2022), using stem cell technology is currently gaining momentum as a promising approach for enhancing medical treatments. Stem cells exist in adult somatic cells and human embryos. These cells are located in various parts of the body and aid in maintaining healthy cell populations and replacing dying or damaged cells. This included bone marrow, umbilical cord blood, adipose tissue (used for fat storage), and amniotic fluid (fluid encircling a foetus) (Hoang et al., 2022).

Embryonic stem cells (ESCs) function as the foundational cells from which all 220 cell types that make up the human body develop. Upon fertilisation by a sperm, the egg transforms into a zygote. This zygote then proceeds to undergo successive rounds of cell division, forming a morula. Subsequently, the morula develops into a blastocyst (Fadel, 2012). This latter quality, pluripotent, makes them a promising candidate for use in regenerative medicine (Mahmoud, 2022).

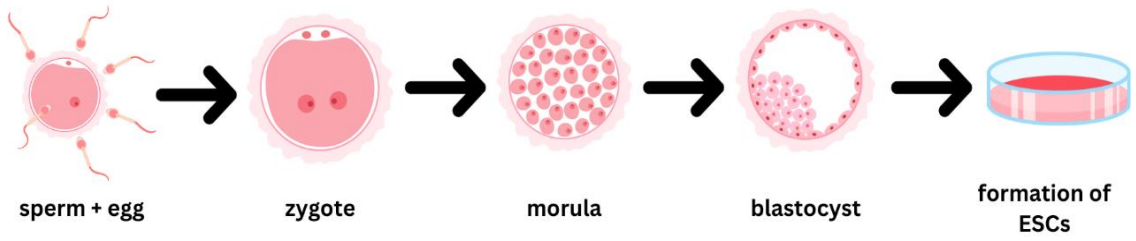

Figure 1: Formation of Embryonic Stem Cells (ESCs)

ESCs have two types (Mahmoud, 2022):

1. Naturally Generated Human Embryos - ESCs are created by fertilised eggs in a lab through a series of carefully monitored and regulated phases of culturing and differentiation.
2. Artificially Generated Human Embryos (Embryoids) - scientists specialising in the fields of genetics and developmental biology have successfully created laboratory models of early human embryos, commonly referred to as "embryoids", through the utilisation of pluripotent stem cells to avoid the controversy of endangering the

embryo's life in the process. These synthetic organisms having embryo-like characteristics (pluripotent cells) are known as artificial embryos or embryoids and are not the result of fertilisation.

i. Somatic Cell Nuclear Transfer (SCNT) - technique utilised in the field of regenerative medicine and reproductive cloning.

ii. Induced Pluripotent Stem Cells (iPSCs) - derived from adult skin cells through genetic reprogramming, hence avoiding the necessity for human embryos.

One of the functions of stem cell technology is the potential to serve as a means of treatment by replacing damaged cells with stem cells that can differentiate into healthy new cells (Fauziah & Mukhlis, 2019). By examining ESC lines from cloned embryos derived from the cells of humans with various diseases, it may be possible to understand the molecular causes of the disease better (Mahmoud, 2022).

Their properties make them advantageous for research and treatment, particularly regenerative medicine. It is currently being employed in the medical and biological sectors to explore optimal approaches for treating challenging diseases, including leukaemia, Alzheimer's disease, type 1 diabetes (specifically targeting pancreatic beta islet cells) (Fadel, 2012), and Parkinson's disease (Walters, 2004). In addition, it will facilitate the investigation of basic cellular biology, including the processes involved in fertilisation, implantation, and embryonic development. This information has the potential to be utilised in the management of infertility, recurrent miscarriages, and other related conditions (Fadel, 2012).

Furthermore, the research has the potential to facilitate investigations into the effectiveness and adverse effects of pharmaceuticals, specifically concerning the embryonic development of humans (embryotoxicity), and it aims to prevent occurrences similar to the thalidomide tragedy back in the 50s and 60s (Fadel, 2012). Other than that, as cited by Rizka and Budiwati (2022), Kalthoff (2001) claimed that stem cell therapy holds significant potential not just in addressing a range of previously untreatable degenerative disorders but also in facilitating the reversal of ageing, resulting in enhanced youthfulness, aesthetic appeal, vitality, and physical fitness.

3. Problem Statement

The predominant focus of stem cell research is ESCs, which present significant ethical, legal, and societal concerns (Fauziah & Mukhlis, 2019; Lye et al., 2015). This is mainly due to the necessity of embryo destruction for cell acquisition (Aksoy, 2005), and the issue in question is whether such actions can be classified as murder. It is widely recognised that the human life cycle consists of distinct stages:

Figure 2. Stages of the Human Life Cycle

To acquire ESCs, it is necessary to terminate the development of an embryo between 5 and 7 days old and already possess the characteristics indicative of human nature. The

main issue is whether the embryo at the stage of 5-7 days old can be considered a human being with inherent rights to safeguard it from harm or destruction.

Moral philosophers have different perspectives of view. Some believe the zygote has full moral status and should not be used for research or destroyed. Some argue that an embryo has no moral worth because it is only a collection of cells. However, the prevailing view among moral philosophers takes a more nuanced approach, holding that while the zygote has moral standing, it may not be protected until later in its development. This is also the same case with the theologians. They hold diverse opinions on the moral worth of an embryo and whether it is acceptable to intervene with one, and their viewpoints are based on their conceptions of how human life began. Taoism, the Catholic Church, the Greek and Coptic Orthodox Churches, and the more conservative Protestant Churches all opposed it. Nonetheless, ESC research has generally received support from Hindu and Buddhist religious organisations and Judaism (Fadel, 2012).

As for Islam, being a religion founded upon principles of moral and ethical excellence, inevitably encounters divergent perspectives on this matter. Extracting stem cells raises ethical and religious concerns due to the inherent damage and destruction of embryonic stem cells involved in the process. The religious and ethical evaluation of research with pluripotent cells obtained from human embryos in Islam can be inferred by examining the Shariah principles about the fetus's viability and the embryo's sacredness (Fauziah & Mukhlis, 2019). As stated by Ilkilic & Ertin (2010), several researchers have identified similarities between the utilisation of embryos in the field of stem cell research and the procedure of abortion, arguing that the embryos have the potential to develop into viable humans on par with those implanted in the womb of a pregnant woman and should therefore be protected from being destroyed during the research process.

Furthermore, the Eubios Declaration on International Bioethics meeting in 2002 outlined the potential usefulness of ESCs as a medical intervention for generating tissues or organs. The importance of only using this method when essential and requested by patients was highlighted. However, unless ESCs can be declared technically sound and a global consensus can be achieved over the ethical boundaries limiting its authorised applications, it is essential to refrain from exploring them (Macer, n.d.).

Not only that, but it is also crucial that no part of the human body be used for commercial benefit, including the DNA, gametes, genes, cells, tissues, and organs. Human organ trade, unethical drug testing, and improper waste management (including nuclear waste) are all examples of such practices (Macer, n.d.). As a result of the circumstances mentioned above, there is a pressing need to find alternatives to embryo destruction to obtain stem cells.

Some medical facilities, for instance, offer unlicensed treatments. The study mentioned above by Rizka and Budiwati (2022) examines the controversial practice of administering illicit stem cells to individuals for beautification purposes. The individuals involved have purchased and vented stem cells for US$16 thousand to their targets. The Stem Cell Serum is sourced from Japan and was promptly transported to the medical facility for expeditious administration to the individual. Currently, the three individuals who have been apprehended may potentially face legal consequences under various articles of the Criminal Code.

Lastly, the field of stem cell technology has generated considerable controversy due to the desire of numerous researchers to advance the development of ESCs, which hold significant potential for various benefits. However, this pursuit has raised concerns, particularly with the irreversible nature of genetically modified organisms once they are created (Fauziah & Mukhlis, 2019). One of the limitations associated with this form of

cloning pertains to the concern surrounding the striking similarities observed between stem cells and cancer cells. Both types of cells possess the capacity for unlimited growth, and several studies indicate that stem cells may collect mutations that have the potential to result in the development of cancer after undergoing 60 cycles of cell division (Bjerkvig et al., 2005).

4. Materials and Methods

This research used a qualitative design to gain in-depth knowledge about the topic under study and the possibility of utilising stem cells in biomedical treatment. The reason for this research to be conducted in a qualitative design is due to the characteristics of the approach that comprehends the research conducted by various researchers. Not only that, but the qualitative design also offers a far more adaptable approach, allowing researchers to modify research questions to gather necessary information (Bhandari, 2020). Thus, utilising this qualitative design can achieve the research objectives of this research which are:

1. To examine the Islamic legal perspective regarding using stem cells in biomedical treatment.
2. To determine the permissibility of stem cells within the framework of Islamic teachings.
3. To explore any potential restrictions or limitations associated with these applications.

Data were collected from secondary sources by reviewing the existing literature or data from previous research. Utilising secondary sources allows for further understanding of how previous researchers approached the studied topic and allows for data collection in a shorter period (Bouchrika, 2023). This research mainly retrieved the materials from academically reviewed journals, articles, books, conference proceedings, published guidelines, and laws.

Searching for materials involves identifying the relevant studies that align with the research topic, objectives, and questions. The materials were sourced from Google Scholar, Emerald Insight, Taylor and Francis Online, Science Hub and Research Gate. In analysing the data, thematic analysis was utilised to obtain information regarding the topic through analysing several data based on the themes. Vaismoradi et al. (2013) defined thematic analysis as a technique for finding, evaluating, and summarising patterns (themes) in data. Therefore, specific themes highlighted in the materials reviewed were “stem cells”, “biomedical treatment”, “permissibility” and “religious compliance”.

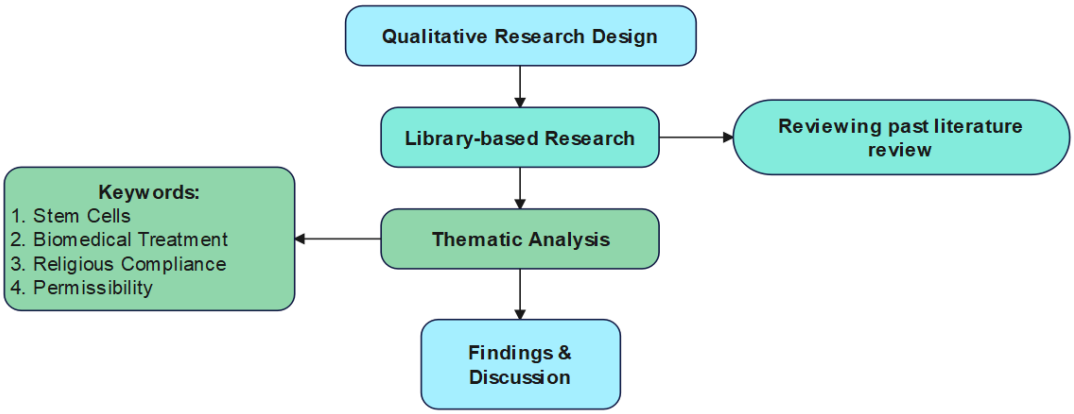

Figure 3. Research Methodology

5. Results and Discussions

Biomedical operations have seen various advancements, with the utilisation of stem cells constituting the current technological advancements. However, since these advancements were not discovered during the Prophetic period, the decisions and issues surrounding the utilisation of stem cells were not addressed in the past as they did not exist (Mazri, 2020). Islam, a religion that embraces innovation in biomedicine, should lay down regulations based on the Qur'an and Sunnah. If the law contains no explicit prohibitions, then there should be no obstacles to considering the innovations (Al-Hayani, 2008). If the treatment can cure the patients, it is complying with the *Maqasid Shari'ah*, which is to preserve life (*Hifz an-Nafs*). It correlates with what surah al-Baqarah, verse 185, Allah SWT has reaffirmed:

﴿ يُرِيدُ اللَّهُ بِكُمُ الْيُسْرَ وَلَا يُرِيدُ بِكُمُ الْعُسْرَ وَلِتُكْمِلُوا الْعِدَّةَ وَلِتُكَبِّرُوا اللَّهَ عَلَى مَا هَدَاكُمْ وَلَعَلَّكُمْ تَشْكُرُون...﴾

> *Translation: "... Allah intends for you ease and does not intend for you hardship and [wants] for you to complete the period and to glorify Allah for that [to] which He has guided you, and perhaps you will be grateful".*

As previously noted, stem cells can be employed for treatment or research; however, it depends on whether ESCs are being utilised. Scholars widely acknowledge that stem cells possess significant potential for research and treatment purposes, intending to mitigate diseases and enhance the overall quality of life (Sajuri, 2006; Mazri, 2020). The Malaysian government has implemented regulations regarding stem cell research and therapy. These rules stipulate that ethical norms must be duly considered in all assessments and therapeutic trials about stem cells. Furthermore, the guidelines permitted the use of non-human cells, human adult cells, ESCs derived from excess embryos, and stem cells obtained from foetal tissues resulting from legally conducted pregnancy terminations (Medical Development Division, 2009).

In their published article, Isasi and Knoppers (2006) provided evidence to bolster the previous claim, highlighting that even though only a few countries outright forbade the research, most countries where public policies were implemented permitted it, but under stringent conditions. Al-Aqeel (2009) contends that stem cell research for therapeutic purposes is acceptable so long as the pre-ensoulment stages occur during the early stages of foetal development and are sourced from reliable sources. Furthermore, a consensus among most Muslim scholars exists, affirming the permissibility of researching pre-embryos, namely pre-implantation embryos, if they were not intentionally created for research purposes but were properly formed (Fadel, 2012).

According to Al-Hayani's (2008) publication, the Muslim president of the Egyptian Medical Syndicate holds an opinion opposing the utilisation of embryos in stem cell research due to his belief that it is morally wrong, unethical, and conflicts with Islamic principles. Added to that, there are several limitations in the previously mentioned guidelines where researching stem cells is prohibited, including:

1. Research involving the in vitro culture of intact human embryos, regardless of the method of derivation, for longer than 14 days or until the primitive streak begins, whichever comes first;
2. Research involving the implementation of ESCs into non-human primate blastocysts or the implementation of any ESCs into human blastocysts;

3. Reproduction should not be permitted in any animal that has been introduced at any stage of development for ESCs;
4. Fusion of ESCs or other pluripotent nature with cells of non-human origin shall not be allowed to develop for longer than 14 days or until the primitive streak begins, whichever comes first (Medical Development Division, 2009).

5.1 Islamic Ruling on Stem Cells Therapy

From a medical perspective, stem cell therapy can be categorised into two distinct classifications: (1) for the treatment of degenerative diseases, genetic disorders, and damage to nerves and tissue cells and; (2) to prevent measures of reverse ageing treatment. Generally, stem cell therapy is used as a treatment for diseases. There are various sources of stem cells; some are those obtained from placenta or umbilical cord blood, foetal tissue, somatic cells, and adults. These sources of stem cells are accepted only with the owners' consent (M. Albar, n.d.).

In Islam, the lawfulness of ESC research is determined by the benefits received from such applications, although it remains controversial. The religious status of the embryo is decided differently depending on the time of ensoulment. The moral condition of the embryo and the beginning of life is taken into account in Islamic ethics and jurisprudence. The Islamic perspective allows ESC research to be used under certain conditions, taking into account medicinal characteristics and crucial therapeutic reasons. According to Islamic belief, the soul of a foetus develops only at 120 days of pregnancy, which enables the use of foetuses younger than 120 days to be used in research. Moreover, using spare embryos for therapeutic research to address severe human diseases is permitted under *dharurah* and *rukhsah* (Anuar et al., 2018).

As per the statement of the Fatwa Committee of Singapore, Islam does not ascribe any evaluative viewpoint towards an embryo during its embryonic developmental phases. In Islam, a soul is believed to be implanted into the embryo at four months of age, which is approximately around 120 days. Hence, an embryo is only regarded as a human life after that point. As a result, an embryo that is less than four months old, whether inside or outside the womb, is regarded as a developing living organism. However, the existence of a soul is not yet regarded as the start of human life. This is clearly stated in Surah Al-Isra', verse 85:

﴿وَيَسْأَلُونَكَ عَنِ الرُّوحِ ۖ قُلِ الرُّوحُ مِنْ أَمْرِ رَبِّي وَمَا أُوتِيتُمْ مِنَ الْعِلْمِ إِلَّا قَلِيلًا﴾

Translation: "And they ask you about the soul. Say: The soul is one of the commands of my Lord, and you are not given aught of knowledge but a little".

However, according to another hadith narrated by Huzaifa Ibn Aseed, the point of demarcation and the commencement of human existence is thought to be 40 days from the time of conception (M. A. Albar, 2001). This is supported by the hadith of Prophet Muhammad SAW narrated by Abdullah bin Mas'ud:

"(The matter of the Creation of) a human being is put together in the mother's womb in forty days, and then he becomes a clot of thick blood for a similar period, and then a piece of flesh for a similar period."

The utilisation of stem cells raises the question of whether such therapeutic practises follow the divine law established by Allah SWT. There are no clear verses in the Quran or Sunnah that either authorise or ban the use of stem cells; hence, the Islamic decision on stem

cell research and therapy depends on comprehending the verses and interpretation of those sources. Nevertheless, it is crucial to acknowledge that when engaging in Islamic research, it is imperative to assess the extensive ethical framework established in the Qur'an and Sunnah and to utilise knowledge to uphold fairness and justice for all of humanity. Academic researchers emphasise the imperative of adhering to fundamental principles, including compassion, mercy, and promoting unified welfare.

Therefore, in general, most Islamic scholars favour stem cell research and therapy that serves to advance and preserve the greater good. Future medical advancements will be able to improve humanity's standard of living, and this shows that the advantages of stem cell therapy outweigh its drawbacks. This pertains to the resolutions made by the *al-Majma' al-Fiqh al-Islami* conference that took place in Makkah al-Mukarramah in December of 2003, which stated that stem cell therapy is permitted as long as the donor or the recipient will not experience any harm or expected harm, the procedure carried out with approval from responsible adult or legally recognised guardians of a minor under Islamic law and the outcome of the procedures will result in favourable circumstances.

There are five objectives of *Maqasid Shari'ah*, which are (1) protection of life, (2) protection of property, (3) protection of health, (4) protection of religion, (5) protection of dignity and there are three levels of necessity under *Maqasid Shar'iah* which are (i) Necessities (al-*Dharuriyat*); (ii) Needs (al-*Hajiyat*) and; (iii) Luxuries (al-*Tahsinat*). Therefore, stem cell therapy falls under the protection of life and protection of health under the category of Necessities (al-*Dharuriyat*), as it may help patients with chronic diseases live longer or be healthier (Alimin et al., 2016).

The therapeutic use of stem cells is sanctioned by *Qawa'id Fiqhiyyah* (Legal Maxims) in addition to *Maqasid Shari'ah*. Stem cells are recognised as a human body component and have been shown to provide substantial medical benefits (Iffatin, 2020). This points to the first legal maxim, "*al-Aslu fi al-Ashya' al-ibaha"* الأصل في الأشياء الإباحة which implies that everything is permissible based on rules. There are no religious directives about stem cells mentioned in the Qur'an or Sunnah that dictate the status or prohibition of stem cell usage. However, Allah SWT allowed the use of stem cells to save one's life, which is regarded as having a noble value (Ali et al., 2017).

The second legal maxim, *"al-mashaqqah tajlib al-taysir"* المشقة تجلب التيسر (hardship begets facility), is pertinent to the application of stem cells. In this case, "hardship" implies the situation that eliminates all legal obligations upon its occurrence. On the other hand, providing the facility or lessening the burden is not significantly impacted by a hardship that does not result in the lightening of religious responsibilities. According to this maxim, there are ways to prevail over obstacles and hardships an individual faces in the situation that a law's execution creates (Chamsi-Pasha & Albar, 2019). It has been discovered that there are more accessible and more effective alternatives to surgery when it comes to the use of stem cells for patients with any kind of disease (Iffatin, 2020).

The third legal maxim thereby states that in an emergency circumstance where one's life is in danger, one may take something that is generally forbidden to save oneself. This is known as *"al-darurat tubih al-mahzurat"* الضرورة تبيح المحظورات (necessity permits (makes lawful) prohibitions). In *Usul al-Fiqh*, this permission is referred to as *rukhsah*, and there are varying degrees of religious rulings about its use (Ali et al., 2017). Menstrual blood, for example, is significantly unclean (*najis*) when used as a source of stem cells. However, if the blood includes cells that can treat specific illnesses, utilising it is permissible under the emergency

approach (Iffatin, 2020). Nonetheless, it is essential to remain mindful of the maxim *"al-darurah tuqaddar bi qadariha"* الضرورة تقدر بقدرها (necessity dictates exception), which states that stem cell use should only be limited to what is required in a dire situation.

5.2 Fatwa on Stem Cells Therapy in Selected ASEAN Countries

5.2.1 Singapore

Singapore has made major investments in stem cell research as a part of its biomedical science to boost its economy. Singapore aims to create and develop cell-based treatments for diabetes, heart failure, eye disease, and other degenerative conditions. For instance, preclinical research with rabbits and pigs and early clinical trials use natural ESC transplants for cartilage repair and autologous transplants of human conjunctival and limbal stem cell transplants for corneal injuries. These are some of the advancements made in Singapore on stem cells.

When it comes to fatwa regarding the usage of stem cells in Singapore, according to the Bioethics Advisory Committee (BAC), the utilisation of embryos derived from in-vitro fertilisation (IVF) procedures, specifically those that are younger than 14 days, is deemed ethically permissible solely to conduct stem cell research, with the ultimate goal of advancing the welfare of the general population. According to the Fatwa Community, academic research on the human genome, genetic engineering, and other relevant topics is encouraged in Islam. However, such research must be used to benefit humanity in areas such as treatment for illnesses. This is on the condition that it is not misused for human reproductive cloning, which would cause the exploitation of offspring and the degradation of human dignity.

Moreover, to conduct research, it must adhere to the Islamic Jurisprudence principles or legal maxims, which are (1) it does not cause any harm or intended to cause harm and (2) harm should be avoided. The first principle means that it should not cause any harm to oneself and others, and it does not benefit oneself but causes harm to others. While the second principle means that harm may occur, it should be avoided before or after. Therefore, the Fatwa Committee of Singapore ruled that stem cells from embryos below 14 days old to be used for research is allowed in Islam as long as it is not misused for human cloning, which will cause a loss of human dignity.

5.2.2 Malaysia

In Malaysia, haemopoietic stem cells (HSC) are one of the main focuses of stem cell research. These cells are found in bone marrow, peripheral blood, and cord blood. Compared to ESCs, these cells have minimal ethical concerns. Because of this, utilising sources other than adipose-derived stem cells and umbilical cord blood stem cells, such as fertilised embryos, remains a significant problem in Malaysia. However, Malaysia's Ministry of Health acknowledges the significance of stem cell research and promotes local researchers' participation as long as the research complies with ethical standards.

According to a study by Imran (2022), the sources of stem cells should mostly consist of adult stem cells, a foetus that is aborted spontaneously or miscarried, and the procedures must not cause harm to people or oneself. This statement is substantiated by a fatwa issued in Negeri Selangor, wherein the Mufti Department of Selangor has issued an official declaration stating that stem cells obtained from specific sources are deemed legal for utilisation in the domains of therapy, medical care, and research through fatwa legislation

No.13. The sources of stem cells are specified as (1) from adult stem cells with consent and the procedures do not cause harm; (2) from a child with parents' consent and the procedures do not cause harm; (3) from the placenta and umbilical cord blood of baby with parents' consent; (4) from a spontaneous abortion or miscarriage as a result of medical treatment that is permitted by Shariah, with parents' consent and; (5) from excess embryos stored frozen from IVF fertility assistance technology with parents' consent.

Moreover, the National Fatwa Deliberation Committee had issued a ruling regarding stem cell research whereby (1) human cloning for any reason is prohibited because it goes against the nature of humans, whom Allah SWT created, and (2) the use of stem cells for medical research in studies that do not involve cloning is necessary as long as it does not go against the Shariah law.

Furthermore, Malaysia has established a comprehensive stem cell research and therapy guideline called the Malaysia Medical Council (MMC) Guideline 002/2009. Stem cell therapies, including embryonic or adult cells, are still experimental and subject to ongoing research. Consequently, getting a permit from the Ministry of Health (MOH) is imperative to ensure compliance with the prescribed procedures outlined in the MOH Guidelines, as adherence to these guidelines is of utmost importance. The standards are as follows;

i. HSC and umbilical cord stem cell transplantations are the most established form of stem cell therapy. The current indications for HSC therapy are listed in the National Guidelines for Haemopoietic Stem Cell Therapy, 2009, and the National Standards for Cord Blood Banking and Transplantation, 2008
ii. A registered medical practitioner with training and experience in immuno-genetics or transplantation, basic or clinical immunology, immuno-haematology, blood or tissue banking, or cryobiology, shall be the director of a Cord Blood Bank (CBB), whether in a public or private facility. The CBB Director is responsible for the CBB's scientific and clinical performance and overall compliance with the standards and structure required of such CBB, as laid down by the Ministry of Health Malaysia (National Standards for Cord Blood Banking and Transplantation, MOH, 2008).
iii. Any treatment involving stem cells shall only be carried out by a registered medical practitioner, who will be required to comply with the Guidelines issued by the Ministry of Health Malaysia and the Code of Professional Conduct and related Guidelines of the Malaysian Medical Council, and all related statutes of Malaysia including the Private Healthcare Facilities and Services 1998 and the Regulations 2006.

Furthermore, private stem cell facilities have been developed due to the growing interest in stem cell transplantation. Such laboratories must adhere to all applicable laws and rules and must be supervised and controlled by a licensed medical professional who is responsible for all operational aspects of such processes.

However, a study by Gopalan et al. (2019) found that Malaysia's present guidelines for stem cell research and therapy are insufficient to ensure the ethical management of stem cell technology. This is because private medical clinics or laboratories that provide stem cell therapies are likely to engage in more unethical behaviour. Moreover, they urge a thorough review of Malaysia's current stem cell policy to control the open practices of private and public stem cell industries. Moreover, it was suggested that the recently updated Malaysian stem cell guidelines follow the International Society for Stem Cell Research (ISSCR) Guidelines for Stem Cell Research and Clinical Translation 2016, which contain moral principles that are both secular and universal. The updated guidelines are also recommended to ensure moral oversight and control of Malaysia's stem cell industry.

5.2.3 Indonesia

Indonesia is moderately active in the area of regenerative medicine, especially stem cell therapy. In Indonesia, hospitals and private physician organisations have established clinics for personalised medicine that offer a range of cells for diverse applications. Although it is legal, some clinics in Indonesia are not well-regulated and may make misleading claims.

The utilisation of stem cell therapy for medical treatments is typically permissible in accordance with the legal framework in Indonesia. Nevertheless, there exist stringent prerequisites that must be adhered to. With the enactment of Act No. 36 of 2009 on Health and the subsequent issuance of many regulations by the Indonesian Minister of Health as its implementing rules, the Indonesian government established the use of stem cells as a kind of medical therapy. For instance, Indonesia has implemented Health Ministry Regulation No. 833/MENKES/PER/IX/2009 on the Implementation of Stem Cell Services where the government understood that stem cells were crucial for treating genetic and degenerative diseases due to the rapid advancement of research and medical technologies. Moreover, the government aimed to protect patients' or stem cell users' rights through the regulation so that the public health sector could offer better services. Indonesia has also implemented Health Ministry Decree No. 834/MENKES/SK/IX/2009 on Guidelines for the Implementation of Medical Stem Cell Services, which plays a significant role in regulating the use of stem cells due to its comprehensive and helpful instruction that includes a wide range of topics such as legal framework and medical stem cell services for stem cell service providers (Utomo, 2013).

Subsequently, the aforementioned regulations were deemed null and void subsequent to the release of the Regulation of the Minister of Health of the Republic of Indonesia Number 32 of 2014 concerning the Establishment of a Central Hospital for the Development of Medical Services for Research and Education of Tissue and Stem Cell Banks and the Regulation of the Minister of Health of the Republic of Indonesia Number 48 of 2012 concerning the Implementation of Cord Blood Stem Cell Banks Center (Lestari et al., 2023). The most recent regulations are the Minister of Health Regulation No. 62 of 2013 concerning the Management of Bank of Tissues Cells and No. 32 of 2018 concerning the Management of Stem Cells and/or Cells Services. Therefore, using stem cells for medical treatment and humanitarian reasons is legal but should not be used in human reproduction (Iffatin, 2020).

According to a fatwa issued by the Majelis Ulama Indonesia, No. 51 of 2020 stated that generally, using ESCs for any purposes is haram due to (1) stem cells taken from ESCs from not legally married couples, (2) stem cells taken from the foetus that have been miscarried intentionally and/or without medical reasons and; (3) stem cells taken from foetus that are intentionally aborted to be used as a source of stem cells. However, using ESCs is permissible if there is a need for conditions: (1) treatment for various diseases; (2) reconstructive therapy or restoration of tissue of organs resulting from trauma or disability; and (3) medical research. Therefore, stem cells obtained from (1) foetus from spontaneous abortion or aborted for medical indications; (2) obtained from unused remaining embryos in IVF with consent of parents; (3) obtained from umbilical cord with consent from parents; (4) obtained from children's cells with consent from parents and; (5) obtained from adult human cells with agreement and consent are permissible to be used as a treatment for diseases.

5.2.4 Brunei

There are no specific mentions of stem cells in Brunei, and it is unclear whether there are any specific studies of stem cells in Brunei. However, a cord blood stem cell bank exists in Brunei, which the Malaysian Ministry of Health fully authorises. The first private cord blood stem cell bank under the Private Healthcare Facilities and Services (PHFS) Act of 1998 is named StemLife Berhad. It was founded in 2001 under a division of the Cordlife Group, a consumer healthcare company listed on the Main Board of the Singapore Exchange. The company has released over 500 peripheral blood stem cell units for therapeutic use and 71 cord blood units for transplant use. StemLife Berhad offers various services, such as umbilical cord lining, to treat stroke, cardiovascular diseases, autism, and other conditions, as well as non-invasive prenatal testing. This maternal blood test screens chromosomal abnormalities as early as ten weeks of pregnancy.

The Stemlife Cell Banking Resources Centre is in Jerudong Park Medical Centre (JPMC), Brunei Darussalam. It helps to assist Bruneian expectant parents in better-comprehending stem cell banking as well as how their family members can gain from stem cell treatments and therapies. It provides expectant families with a straightforward approach to learning more about the lifesaving clinical uses of stem cells from umbilical cord blood. This enables expectant families to make an informed choice before the birth of their child. The collection procedure for umbilical cord and cord blood is simple and quick. The cord blood and umbilical cord are collected, processed, and transferred right away to Stemlife's American Association of Blood Bank (AABB), a licensed facility in Malaysia for long-term cryopreservation. Parents who store their babies' cells will benefit from not only the current achievements in research and cures but also any future discoveries that may be made because once cord blood is removed and frozen, it remains viable for usage for decades.

Concerning the fatwa being issued regarding the permissibility of stem cell therapy, there is currently no fatwa being issued by Mufti Brunei on this matter. Moreover, no laws and regulations on the issue of stem cell therapy are yet to be enforced in Brunei. However, based on the stem cell bank, it is assumed that stem cell therapy is acceptable in Brunei even though there are no guidelines or fatwa relating to its usage. Nevertheless, further research and clarification must be made by the government authorities to clarify this matter further.

5.3 Recommendations

Evaluation of a new product's safety is one of the most crucial concerns concerning its introduction to be used by humans through a clinical trial. Despite being a relatively recent addition to the therapeutic environment in medicine, stem-cell-based therapies have garnered significant attention in clinical trials for their potential to treat a wide range of disorders. Nevertheless, introducing new stem-cell-based therapies to the market poses significant challenges due to the many characteristics that must be considered. Concerns for treatments based on stem cells include DNA instability following lengthy development, stem cell movement to the wrong areas of the body, immunological reactions, and more. The type of stem cell, the circumstance, the delivery process, and numerous other factors influence each challenge differently. Moreover, issues of stem cells need to be addressed appropriately regarding their usage and limitations.

Additionally, The U.S. The Food and Drug Administration (FDA) is concerned that some patients looking for treatments and cures could be at risk of receiving unauthorised and hazardous stem cell procedures. Therefore, the FDA is stepping up its oversight and enforcement to safeguard the public from dishonest and unethical stem cell clinics while continuing to support innovation so that the medical sector may fully realise the potential of

stem cell products. The FDA recently issued regulatory guidelines to guarantee the effectiveness and safety of stem cell therapy. To facilitate the progress of stem cell modification and the advancement of technology for clinical trial investigations, various entities such as government agencies, industries, corporations, individuals, universities, and private groups must make substantial investments in the growth of the regenerative medicine sector.

Furthermore, improving educational and regulatory initiatives on both a national and international level is crucial. Professional guidelines, such as those issued by the ISSCR, should be formalised into international governmental legislation while recognising the variations in legal systems across different countries. Creating a global accreditation system run by the Joint Commission International or the World Health Organisation (WHO) is necessary. Moreover, National authorities should take action against clinics that break laws governing precise advertising and impose penalties on those who make fraudulent claims (Lyons et al., 2022).

Therefore, the need to create regulatory rules and standards to guarantee patient safety is becoming more and more critical as the number of clinical trials using stem cells as therapeutic methods also increases. Guidelines on stem cell therapy must be implemented by all countries for stem cell research to be ethical and permissible, especially in Muslim countries where fatwa or laws are not being enforced in the country. For example, in Brunei Darussalam, since there are no available guidelines and fatwa regarding stem cell therapy, it is suggested that the government should consider adopting the same guidelines for stem cell therapy, such as the guidelines in Malaysia or the guidelines from the ISSCR. This is to clarify stem cell therapy's status and ensure that the procedures are ethical.

6. Conclusion

Stem cell therapy is known for its regenerative characteristics that can facilitate the formation of cells into various types and offer an optimistic strategy for resolving injuries and illnesses. This therapeutic method plays a significant role in the growth, development, maintenance, and repair of various physiological organs and tissues, demonstrating its significant therapeutic potential in treating illnesses caused by tissue depletion.

Moreover, recent advancements in stem cell research and therapy have opened a new door for patients suffering from medical conditions for which a cure has not yet been found. This has caused an increase in research on stem cell therapy to help find the cure for such illnesses. Despite the numerous difficulties encountered, the potential uses of stem cells are expanding with each scientific study and are quite encouraging.

From an Islamic perspective, scholars have expressed an optimistic stance towards the utilisation of stem cells for therapeutic purposes, provided that such applications yield advantages for humanity and do not inflict harm upon individuals or society. Concerning the fatwa issued by Muslim scholars, only a few ASEAN countries clearly state that stem cell therapy is permissible under certain conditions adhered to by Islamic law. Some ASEAN countries have also developed guidelines to ensure the procedures are ethical. However, since stem cell treatment is still relatively new, it is still prone to unresolved ethical, legal, and scientific debates that need to be adequately addressed by relevant authorities.

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