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La science des cellules souches embryonnaires humaines en Iran : une expérience pionnière dans le monde musulman

Human Embryonic Stem Cell Science in Iran: Pioneering in the Muslim World

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Résumé

La recherche sur les cellules souches embryonnaires humaines (CSEh) est un domaine qui a suscité un vif intérêt dans les milieux scientifiques mais aussi financiers. C'est aussi un champ d'investigation source de dilemmes éthiques et de développements politiques encadrant le statut moral de l'embryon humain, les sources d'embryons ou de gamètes humains destinés à la recherche, le clonage ainsi que l'utilisation thérapeutique des cellules souches. Dans le monde musulman, l'Iran, une nation pionnière de la recherche sur les SCEh, a reporté l'établissement d'une nouvelle lignée de cellules souches dès 2003. Ce pays a aussi établi des recommandations éthiques nationales pour la recherche et la thérapie utilisant les cellules souches. Le présent manuscrit décrit le développement de la science entourant les CSEh ainsi que d'autres accomplissements scientifiques et bioéthiques connexes en Iran. Il explique aussi comment la recherche sur les CSEh est à la fois guidée et réglementée par les lois et principes éthiques issus de l'Islam, et montre comment l'expérience d'un pays en développement peut servir d'exemple à d'autres sociétés similaires. Cet article présente ensuite une brève revue de l'état actuel de la recherche et de la réglementation de ce domaine dans certains pays musulmans du Moyen-Orient. En conclusion, on peut argumenter autour du fait que, bien que la science et la religion soient des facteurs clés dans les débats actuels autours des CSEh, d'autres facteurs influencent la manière avec laquelle un nouveau savoir est abordé dans des pays ayant par ailleurs la même obédience religieuse ou des intérêts scientifiques similaires.

Mots-clés

Cellules souches embryonnaires humaines (CSEh); Ethique; Iran; Recherche

Abstract

Human embryonic stem cell (hESC) research is a field that has attracted considerable scientific and financial investment and attention in many countries. It is also a field surrounded by ethical controversies and policy developments concerning the moral status of the human embryo, sourcing of human embryos and gametes for research, cloning as well as stem cell (SC) therapy. In the Muslim world, Iran, as a pioneer country in hESC research, reported the establishment of a new SC line in 2003. The country has also established the national ethical guidelines for SC research and therapy. This paper therefore depicts the development of hESC science, as well as some other relevant

scientific achievements and bioethics in Iran. It also describes how hESC research is both formed and regulated by Islamic law and ethics, as the experience of a developing country can provide insight to many similar societies. This article then presents a brief review of the current state of this field of science and its regulatory policy in some selected Muslim Middle East countries. In conclusion, it shall argue that, although science and religion are key factors in the current debates around hESC research, additional factors influence the manner in which new knowledge is taken up in countries with the same religious background or scientific interests.

Keywords

Human embryonic stem cell (hESC); Ethics; Iran; Research

Introduction

During the last two decades, Iran has heavily invested into science and moved toward a knowledge society with the paradigm of advanced technologies. Research and development (R&D) centres and academic people have recently flourished in multidisciplinary fields such as biotechnology, nanotechnology and stem cell (SC) research and technology. Among these innovative fields, human embryonic stem cell (hESC) science, as a vital interdisciplinary scientific ground with rapid pace of advancement and clinical promises, has attached many young scholars and researchers. Parallel to the developments in the world, there has also numerous initiatives in Iran on SC studies and practices.

The development of hESC research in Iran

In 2002, the *fatwa* (religious opinion of Islamic scholars on special issues) by Iran's Supreme Leader on the admissibility of "the destruction of the left-over embryos from *in-vitro* fertilisation cycle in order to collect stem cells for research" was received as an approval for hESC science community in the country [1]. Following this positive *fatwa*, the Department of Stem Cells in the Royan Institute, Tehran, was founded, in the same year, with the goal of establishing hESC lines and developing techniques to differentiate these lines into various mature cell types, including cardiomyocytes, *B* cells and neural cells [2]. Other research institutes have been also involved in regenerative medicine. These include the Iranian Molecular Medicine Network (with 34 research institutes and centres joined as member), the Iran Polymer and Petrochemical Institute and Shaheed Beheshti University of Medical Sciences [3].

In March 2003, the Islamic Republic News Agency (IRNA), the official Iranian press agency, announced that the country was among the first ten countries in the world that were capable of producing, cultivating and freezing hESCs [4]. Thus, Iran was in the group of countries, such as Sweden, UK, Japan, South Korea, and Singapore, that could produce hESCs, and it was the only Muslim state to do so in the Middle East and North Africa [5,6]. Since then, much research has been conducted in many different areas such as registration of one hESC line in the International Society of Stem Cell Research. Additionally, there has been the establishment of 6 lines of human ESCs and 8 lines of mouse ESCs. Furthermore, Iran has reported hESCs' proteomics for the first time in the world [7]. Moreover, the birth of Royana, the first cloned sheep in Iran, in 2006, and of Hanna, the first cloned goat in the Middle East and the fifth in the world, in 2009, prove that Iran has progressed remarkably in science, and special attention should be paid to this country in medical issues and ethical debates as well [8]. In 2008, Royan Institute scientists claimed that they had also succeeded in reprogramming human skin cells to an embryonic-like state to create so-called induced pluripotent stem (iPS) cells [9]. This field of research, however, raises many ethical dilemmas, in which most disputed is the conflict between the ethical value of the embryo's human life in one hand and on the other hand, the possibilities of medical progress to cure other humans suffering serious illness / save lives of the other.

hESC science policy and ethics

In March 2005, the Supreme Leader endorsed key policy guidelines, called Iran's "20-Year Vision", which had been drafted by the Expediency Council. It outlines a road map for the country's social, cultural, political and economic development for the following two decades. The Vision's preamble promised that by 2025, that is, after the completion of the fourth five-year development plan, Iran would be a fully advanced country, rising to the number-one rank in economic, scientific, and technological fields among 28 nations in the Middle East and South-east Asia [10]. Since the outset, hESC science has received the recognition of policy-makers and regulators as being one of the national priorities in high technologies, inspired by the overarching policy document of "20-Year Vision".

Ayatollah Khamenei, Iran's Supreme Leader often cites the holy *Qur'an* emphasis on preventing human illness and suffering as evidence that SC research and Islam are compatible. Limits do exist: Iran's Supreme Leader has warned Iranian scientists to "be careful that producing identical parts of human beings does not lead to producing a human being," as human cloning is not accepted [11]. With regard to the legality and regularity aspects, the Ministry of Health and Medical Education (MOHME) is in charge of supervising hESC research in Iran. The first set of procedures is based on the decentralised decisions of the in-house ethics committees that are established at all R&D centres and in universities in compliance with the directives of the MOHME. The members of these committees are selected from the internal scientific staff and invited religious consultants. They fulfil their duties by relying on unified guidelines that are drafted and approved under the general title, "Specific National Ethical Guidelines for Biomedical research". The separated parts of the guidelines provide working models on "Clinical Trial", "Genetic Research", "Gamete and Embryo research", and "Research on Animals" [12]. These guidelines were compiled in 2005 by a task force, including in religion, law, ethics, medicine, and related fields of science, initiated by the MOHME, in collaboration with Centre for Medical Ethics and History in Tehran University of Medical Sciences. They have been developed to put into effect ethical codes in research and to protect different stakeholders' rights (e.g. patient research participants or vulnerable groups). Then, the guidelines were communicated to universities and research centres after their adoption by the Policy-Making Council of the MHME, and several committee workshops and educational sessions, which was supposed to be held by universities and research centres, through which the members become familiar with the guidelines [13,14].

Within the specific section on "Gamete and Embryo Research" in the drafts, some general topics include the following: participants' rights, informed consent, ethical review committee's responsibilities, and compensation[1]. Moreover, hESC research and cloning for therapeutic purposes is permissible only during the first 14 days of embryo development with all things duly considered and all possible precautions taken. Some of the principles recommended in the ethical guidelines for "Gamete and Embryo Research" include:

- respect for human dignity and human rights;
- voluntary and informed participation in research, which will not affect a patient's treatment;
- respect for privacy and confidentiality;
- equitable distribution of benefits and harms, especially in research, including clinical treatment;
- prohibition of the production of human embryos for research purposes;
- use of only surplus *in-vitro* fertilisation (IVF) embryos, below 14 days, for research, which includes the destruction of embryos;

1. It is forbidden to pay couples for donating any embryo or gamete for research, except the transportation cost. It is not also permitted to pay for donating good quality or more quantity of embryos for research [see reference 16].

- prohibition of the production of hybrids using humans, animals, and human eugenics;
- responsible people for the embryo being the donor, her partner, and recipients;
- all information regarding research and clinical care of the embryo being made available to responsible people [15].

Although there is no specific framework for hESC research, it does not prevent the related committees from inferring and extracting their frameworks from the letter and spirit of the guidelines.

Iran has recently established the specific ethical guidelines for SC research and therapy, entitled, the "Guidelines on Stem Cell Research and Therapy". These guidelines consist of two main sections: general" and "specific"; and then its "specific" section includes two parts: "research" and "therapy" [16]. In the general section, the guidelines note the importance of establishing the Stem Cell Oversight Committee to periodically monitor the activities of research ethics committees in the SC research institutes and centres in the country. Some other points in this section consist of: the importance of ethical approval for research proposals; informed consent; respect to the human dignity and confidentiality. Moreover, there are some important points about the specific part on SC research, including: the ethical sources for hESC research; the research priorities (which mainly are for research with therapeutic purposes rather than understanding the biological development); benefit sharing of research outputs; and some points surrounding biobanking [16].

hESC science and *Shia*

Iran as an Islamic *Shia* country is founded principally in the *Shari'a* (Islamic law). According to the *Shia* scholars (the Grand Ayatollahs), research is permissible only in the pre-ensoulment (the infusion of the soul into the body of the fetus) stages of fetal development. The holy *Qur'an* states that there is a distinction between the different stages of human development[2]; and Muslim *Sunni* and *Shia* scholars have noted that ensoulment occurs sometimes between 40 days and 120 days, based upon the different interpretations of the *Quran* and *ahadith*[3] (*Singl. hadith:* are the collections of reported sayings and behaviours of the Prophet Mohammad) [17].

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2. Determination of the time of ensoulment is based upon an interpretation of the *Qur'anic* scripture, such as : "He Who created all things in the best way and He began the creation of man from clay; then made his progeny from a quintessence of despised liquid; then He created him in due proportion, and breathed into him of His spirit. And He gave you [the faculties of] hearing and sight and hearts. Little thanks do ye give!" (The holy *Qur'an*, As-Sajdeh, 32:7–9). Another verse passage informs us about the stage of ensoulment during the intrauterine life: "We created man (*khalaqna*) of an extraction of clay, then We set him, a drop (*nutfa)* in a safe lodging (i.e., the womb), then We created of the drop a clot (*'alaqah*), then We created of the clot a tissue (*mudgha*), then We created of the tissue bones (*'azm*), then we covered the bones in flesh (*yaksu lahman*); thereafter We produced it as another creature (*khalaqan akhar*). So blessed be God, the Best of creators (*khaliqin*)" (The holy *Qur'an*, Al-Mu'minun, 23:12–14).

3. For instance: "Verily your creation is on this wise. The constituents of one of you are collected for forty days in his mother's womb; it becomes something that clings [*'alaqa*] in the same [period] [*mithla dhalik*], then it becomes a chewed lump of flesh [*mudgha*] in the same [period] [*mithla dhalik*]. And the angel is sent to him with instructions concerning four things, so the angel writes down his provision [sustenance], his death, his deeds, and whether he will be wretched or fortunate. Then the soul is breathed into him." [Al-Bukhari S. *Al-Sahih, kitab bad' al-Khalq*, vol. 4. Istanbul: Al-Maktaba al-Islami]; 1979. According to this hadith (plur. *ahadith*), each of the first three stages (lodging *nutfa* in the woman's womb, *'alaqa*, and *mudgha*) is assigned a time period of forty days, which makes a total of 120 days. Other *ahadith* differ and give forty days as the total of the four stages [See reference 17].

Some Islamic theologians and bioethicists think there is nothing wrong with hESC research, as it implies destruction of an embryo which is not yet a person. However, any misuse must be carefully observed; for instance, preventing the production of embryos with the very aim to use them in research. If hESC research will show significant potential in helping people then it becomes not only allowed but also mandatory to pursue such research [18]. In Islam, it is a religious duty to carry out research with the aim of developing new medicines and technologies that can benefit humanity. Saving a life is given paramount importance in Islam, as the following verse from the holy *Qur'an* stresses: "... And if any one sustains life, it would be as if he sustained the life of whole humankind ..." [19]. There are also Islamic injunctions that specifically promote education and research in the fields that alleviate the pains of humankind. Because of this and the fact that Islam does not oppose the use of fertilized eggs in research, Iran stands at a considerable advantage when compared to the many countries, even the western countries [20]. In Islam, as noted by Ilkilic and Ertin, "a broad range of arguments is developed in dealing with complex ethical debates, based on the specific nature of Islamic legal and ethical deliberation processes, linked to specific local culture and traditions" [6:p.151].

Status of Embryo and SC Research in Selected Muslim Countries

Although positive attitudes towards scientific research and development seem to prevail in Muslim states in general, this does not mean that there are no significant differences between individual Islamic scholars. In the early part of this chapter, I explained the status of hESC research and its regulation in Iran. The following is a short presentation of the legal and ethical situation of SC science and embryo research in selected Muslim states.

Turkey

Turkey is one of the few secular countries among the Muslim nations. However, Islamic approaches play a significant role in defining its people's opinion on controversial issues in the modern world [6]. This country mostly concentrates on adult SC research, although it has been reported in some relevant studies about hESC research [21,22]. Turkey adopted a permissive approach to allowing researchers to work on the existing hESC lines as well as to create embryos via IVF specifically for research purposes (International Society for Stem Cell Research). They have also recognised national policies related to this field of research, while some other Muslim nations use *fatwas* to guide this research [23]. Moreover, the Turkish Ministry of Health as well as their Bioethics Association prepared several guidelines and reports on various aspects of hESC research [24].

In 2008, the Turkish Academy of Sciences (TÜBA) published the report "Current Concepts in Stem Cell Research," which was prepared by a multidisciplinary Stem Cell Working Group constituted under the auspices of TÜBA [25 cited in reference 6]. The Turkish Religious High Council under the Directorate of Religious Affairs issued a series of opinions on IVF, SCs, and the rights of the fetus, which emphasised that the number of embryos produced during IVF treatment should be kept at a minimum level, as the destruction of surplus embryos, which can be regarded as human beings, raises serious doubts from the religious point of view. Based on this report, "spare" IVF embryos should be reserved for SC research rather than be destroyed. However, the use of embryos at the early stage of development is permissible if it is not possible to obtain SCs with the characteristics of embryonic SCs from differentiated adult cells [26 cited in reference 6].

Arab States

Among Arab nations, hESC science is still debatable, as noted by the UNESCO Cairo Office:

[...] most of these countries lack suitable facilities and equipment for research in this field. Only Egypt, Algeria, Tunisia, and Saudi Arabia have a few non-comprehensive stipulations referring to embryonic stem cell research, whereas the other 13 countries have not yet tackled

this issue. It is important to highlight once again the role that religion plays in decision-making in the Arab world. There are key ethical issues regarding embryonic stem cell research that are nearly impossible to solve, such as the status of the embryo as a human being and the acceptability of research on embryonic stem cells if this means the destruction of the embryo [27].

In this section, three Arab countries, as the examples of Arab world, are briefly discussed: Egypt, Saudi Arabia and Qatar.

Egypt

Egypt has a significant influence on the entire *Sunni* Muslim world through its Islamic institutions as well as its leading role in organising international conferences. Moreover, the main *Sunni* religious authorities reside there, whose *fatwas* are said to be respected by the most of *Sunni* groups [28]. In Egypt the private IVF centre in Cairo mainly uses umbilical cord blood (UCB) for SC research rather than hESCs, as the Egyptian Medical Syndicate opposes the use of embryos for experimentation [29]. Indeed, most of the debates in this country concentrate on human cloning, which is not permitted in the rest of the Muslim world. The mufti of Egypt states that cloning contradicts Islamic legislation and is prohibited in all its forms [28]. However, authorities in Egypt tend to accept therapeutic cloning and hESC research. Along similar lines, the Academy of Scientific Research and Technology as well as the International Islamic Centre for Population Studies and Research at Al-Azhar University, supported the use of surplus IVF embryos for SC research. It seems that they look forward to deriving a possible approach that might adopt hESC research in the future [6]. Presently, there is no official policy on hESC science in Egypt [30].

Saudi Arabia

Saudi Arabia is the most prominently involved in SC science and technology in the Arab world. This country opened the Stem Cell Therapy Program at King Faisal Specialist Hospital and Research Centre in 2007. Later, Saudi Arabia invested many billions of dollars to establish King Abdullah University of Science and Technology in 2009. At the moment, the main sources for SC research are provided by UCB as well as aborted foetuses; and the use of surplus IVF embryos is still being discussed [29]. Saudi Arabia has successfully established reproductive medicine and regulated it by the In-vitro Fertilisation Act (IFA) (No. 2870/1/12) in which they provided a framework for the supervision of clinics. The act also regulates embryo research indirectly and allows storing embryos and gametes with couples' permission [31]. However, there are different views on using a human embryo for research proposes. The *fatwa* issued by the International Islamic *Fiqh* Academy (IIFA) in Jaddah allows the usage of embryos for research on the condition that they not be implanted for pregnancies. Similarly, in 2003 a *fatwa* of the *Fiqh* Council for the Muslim World League permitted researchers to use SCs for therapeutic reasons; another decree of IFA in Mecca prohibits it. Based on the IFA *fatwa*, the creation, storage, and use of hESCs for scientific research is not allowed under *Shari'a* [4,28]). Nonetheless, Saudi Arabia now plans to establish hESCs.

Qatar

Qatar has also decided to launch research on hESCs. It has recently set up Cornell Medical College to establish a SC research laboratory that will be able to expand, maintain, and validate currently available hESCs and develop new SC lines, signaling that its scientists are ready to work on embryonic SCs [32]. According to Qatar national policy, their scientists are allowed to research on SCs which isolated either from the creation of embryos or from spare IVF embryos. However, Qatar current policy on assisted reproductive technologies (ARTs) states that embryos fertilised through IVF are either implanted in woman's womb or frozen for further infertility treatment in the same couple; and affected embryos should be destroyed. Moreover, there is no regulation specifically relating to hESC research in this time [27].

Conclusion

The ethical and religious assessment of the use of human embryos for research in Islam can be inferentially deduced from the rulings of the *Shari'a* that deal with foetal viability and embryonic sanctity in the classical and modern juristic decisions. As technological advances and scientific inventions continue to provide new challenges, Muslim jurists have used the available methods in principles of Islamic jurisprudence in order to find islamically valid solutions. While *fatwa*, according to *Shari'a*, permits human embryo research, this does not, however, mean that there is no restriction. Embryo research and SC science, as noted above, are regulated by Islamic law in different ways in the Muslim countries in the Middle East. Many countries have some form of regulation, for instance, for ARTs, but hardly any of them have governmental regulations for human embryo research and technology, even in a well-established country such as Iran.

The process of adoption of the United Nations Declaration on Human Cloning[4] in 2005 demonstrates the polarisation of worldviews on this controversial topic. It would seem that individual countries have taken up different policies on the use of the embryo for SC research based on their socio-cultural, political, and even economic backgrounds. Hence, as Isasi and Knoppers state, "The historical, cultural and sociological context, the institutional framework, and the mobilisation of stakeholders are factors that help explain why countries that seemingly share similar socio-religious beliefs [and perhaps scientific interest] have adopted diametrically opposite public policies." [20: p. 9]

Iran, as a *Shia* Islamic country, is influenced by the Islamic faith, which is culture-based. The country has resorted to the extensive use of the mechanisms available to Islam, such as *ijtihad*[5], to legitimise some matters in hand, e.g. embryo donation to research purposes. All of these have been justified through interpretations and independent reasoning, which the *Sunni* do not use as much as the *Shia*. For Iran, the introduction of an Islamic system forced religious scholars into an unprecedented role of responsibility and involvement in social planning and public health. For instance, the eight-year Iran-Iraq war had left the country with a large community of disabled people suffering from spinal cord injuries, among others, a fact that provided intensive motivation for Iran to start many cell-therapy research projects [33]. It seems that the financial burden of debilitating diseases also plays an important role in decision making regarding hESC research in this country. Moreover, scientists' technological innovations and achievements hold the hope of a "golden age" for the intellectual and material benefits of the people of Iran, as is often rhetorically used by Iran's Supreme Leader in justifying Iran's position in the Muslim world. Indeed, the consensus of scientists, religious authorities and policy-makers in Iran has paved the way for an evolution in nationwide biotechnology, such as hESC research and therapies.

4. United Nations Declaration on Human Cloning, GA Res., UNGAOR, 59th Sess., UN Doc.A/280. [Internet]. 2005 – [cited 2013 Jul 29]. Available from: http://www.un.org/News/Press/docs/2005/ga10333.doc.htm.

5. The interpretation of one or a few Islamic scholars of a particular age for the legal ruling applicable to the situation.

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