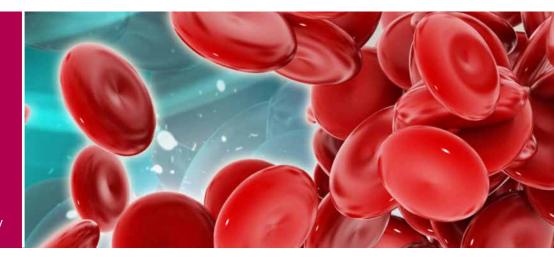


Stem Cell Technology



Stem Cell Technology

I. History and Background

Stem cell research began in the 1950s, when scientists tried to explore new ways to prevent incurable disorders. However, the advancements made in the field proved that stem cells can also be used for tissue repair in tissue engineering and regenerative medicine as well as treatment of genetic diseases and cancer. Thanks to stem cell sciences, it seems that in the near future the humankind will no longer have concerns about the loss of vital tissues.

The history of stem cell research in Iran goes back to the first hematopoietic stem cell transplantation (HSCT) in 1990s. Since 1994, Iranian researchers have published several papers in stem cell-related fields in high impact journals. By 2004, stem cell studies in Iran were developed to include embryonic stem cell research, which led to derivation of new lines of stem cells in the country. Since early 2005, Iranian researchers have also been engaged in tissue engineering and regenerative medicine. Publishing valuable articles in the credible international journals in these fields has been a continuous trend among Iranian researchers ever since.

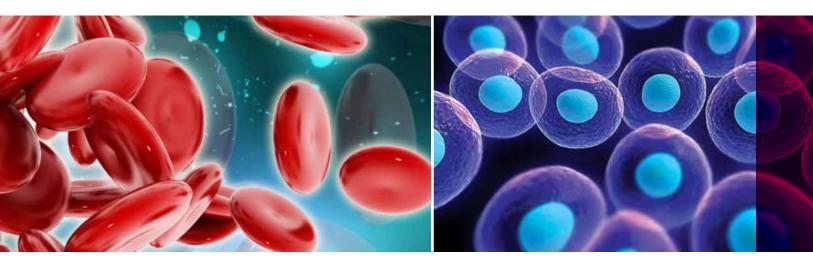
The Council for Stem Cell Sciences and Technologies affiliated to the Iranian Vice-Presidency for Science and Technology was established in February 2009 in an effort to accelerate the county's progress in this strategic area and keep pace with other countries. The national document of stem cell sciences and technologies was also approved as part of the country's national comprehensive scientific map in September 2013 at the Supreme Council of the Cultural Revolution.

Iran's headway towards stem cell sciences and regenerative medicine, despite limited investments, reveals the country's enormous capacity for growth in these fields. In terms of published papers in the field of stem cell sciences and regenerative medicine, the Islamic Republic of Iran is ranked first in the Middle East and Islamic countries and second among the East Mediterranean and North African countries.

It is hoped that upon increase in the investments in stem cell research, Iran would be among the world's top 10 countries by 2025 in terms of science and wealth creation in this novel area of research.

II. Policies and Objectives

Major policies and objectives stipulated in the national document of stem cell sciences and technologies are as follows:



A. Macro Level Policies

- To improve efficiency and cost-effectiveness and make optimum use of the resources in the field of stem cell research;
- To enhance self-reliance and employment, and make maximum use of national capacities in this field;
- To mitigate government's domination, strengthen the private sector, and provide support for the qualitative and quantitative development of knowledge-based companies in the country;
- To encourage participation of the private sector, cooperatives, NGOs and foreign investors in the field with an emphasis on interagency coordination and cohesion;
- To adhere to the Islamic philosophical foundations and jurisprudence;
- To observe the ethical, religious, and social principles for further development of the field.

B. Macro Level Objectives

- To encourage self-reliance in production of the basic materials, laboratory equipment and supplies, and laboratory animals and services with a view to meet at least 50 percent of the domestic demand;
- To enhance national wealth creation through applying stem cells and their products to treat various diseases and to access two percent of stem cell market value in the world;
- To achieve national independence in banking the variety of stem cells;
- To involve the private sector in research, technology development and wealth creation while keeping the policymaking and supervisory role of the government in a way that at least 20 percent of the authorized cell treatment centers would be from the private sector;
- To create new knowledge and technologies with a view to ascend to the world's top ten countries in this field in terms of quality and quantity as well as publishing scientific papers in high credible international journals.

III. Capacities and Capabilities

A. Scientific Productivity

Figure 1 shows total number of scientific articles published in international journals by the country of origin of the authors till the end of 2016. Iran ranked 20th in the world with a total number of 6360 scientific papers in the field of stem cell sciences and regenerative medicine including cell therapy, gene therapy, hematopoietic stem cell transplantation, tissue engineering, and biomaterials.



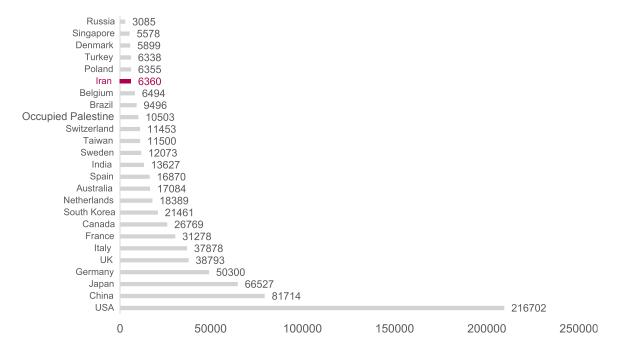


Figure 1: Ranking of the First 25 Countries in Stem Cell and Regenerative Medicine publications (Iran Ranked 20th in the World in terms of Published Articles by the End of 2016 [Source: Scopus, PubMed])

Figure 2 indicates the number of published papers in the field of stem cell sciences and regenerative medicine focusing on cell therapy, gene therapy, tissue engineering and regenerative medicine only in 2016. According to the statistics, Iran ranked 15th in the world with about 1378 scientific articles in the same year.

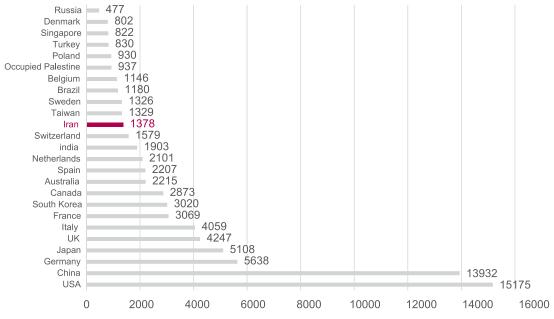


Figure 2: Ranking of the First 25 Countries in Stem Cell and Regenerative Medicine in terms of Published Articles in 2016 (Iran Ranked 15th in the World during January to December 2016)

Figure 3 compares the Middle East and Asia Pacific countries in terms of published papers in different fields of stem cell and regenerative medicine research by the end of 2016. According to the data, Iran ranked 1st in the Middle East and 2nd in the greater Middle East area from eastern Mediterranean to north of Africa with 6360 articles, followed closely by Turkey with 6338 articles.

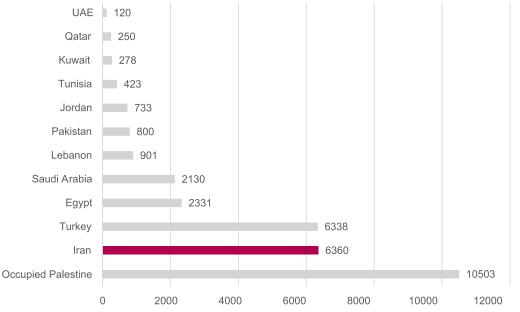
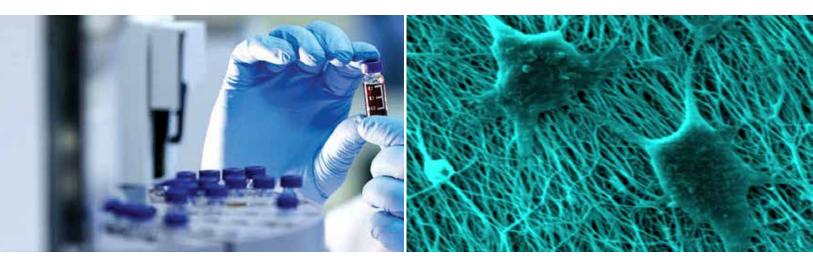


Figure 3: Ranking of Middle East and Asia Pacific Countries in Stem Cell Sciences and Regenerative Medicine Publications (Iran's Scientific Publications in Comparison with the Regional Countries by the End of 2016 [Source: Scopus, PubMed])



In the field of stem cell sciences only, Iran has published about 900 research articles, ranking the second country in the region, followed by Turkey with 800 articles. Figure 4 shows Iran's growth in terms of scientific publications in the field of stem cell sciences, cell therapy, gene therapy, tissue engineering, and regenerative medicine during 2004-15, marking a significant increase in 2011 and 2012 compared to the previous years.

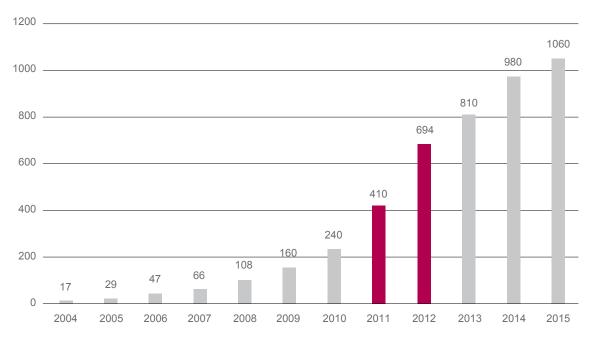


Figure 4: Growth of Iran's Publications in the Field of Stem Cell Sciences, Cell Therapy, Gene Therapy, Tissue Engineering, and Regenerative Medicine by the End of 2015 [Source: Scopus, PubMed]

By 2015, the Islamic Republic of Iran has significantly contributed to knowledge production in the region, with a total of 24 percent scientific outputs (figure 5).

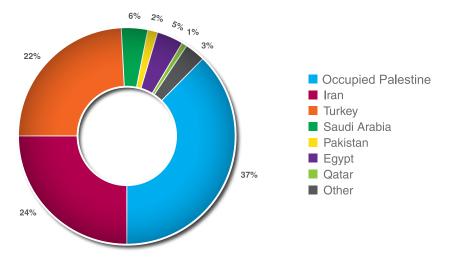


Figure 5: Knowledge-production in Iran by the end of 2015 in Comparison with the Regional Countries in the Field of Stem Cell Sciences

B. Human Resources

The growth of human resources in Iran in the field of stem cell sciences is illustrated in the following figures. Figure 6 represents the number of faculty members in the field. A statistical survey on the centers and universities in this field revealed a growing trend in the number of university graduates, as well as master and PhD dissertations in the field of stem cell sciences, regenerative medicine, and tissue engineering as demonstrated in figures 7 and 8.

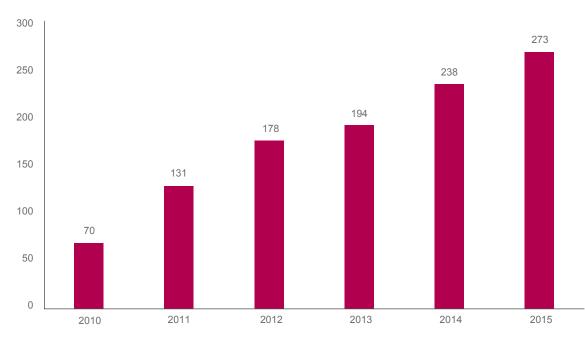


Figure 6: Faculty Members of Iranian Universities and Research Centers Involved in the Field of Stem Cell Sciences and Regenerative Medicine by March 2015

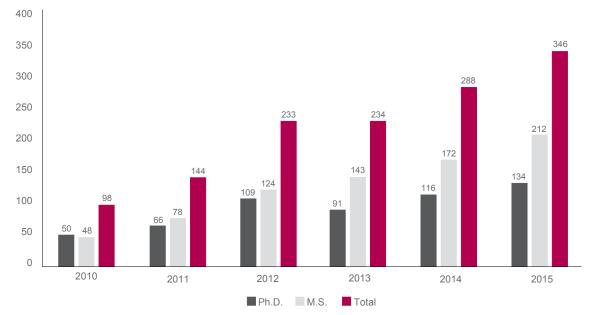


Figure 7: Total Number of Stem Cell Sciences and Regenerative Medicine Postgraduate Students in Iran during 2010-15

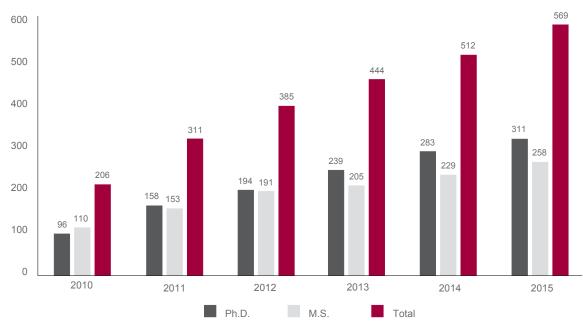


Figure 8: Human Resources in Iranian Universities and Research Centers Involved in the Field of Stem Cell Sciences and Regenerative Medicine during 2010-15

C. Clinical Trials

Clinical trials and evaluation of technology projects are considered important factors to determine the level of advancement in stem cell sciences. In this process, research projects are evaluated and validated before they undergo finalization. In terms of the number of clinical trials in the field of stem cell sciences and cell therapy, Iran ranked the second among the regional countries with 98 registered clinical trials by 2016 (figure 9).

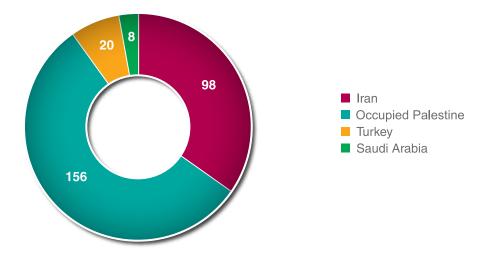


Figure 9: The Number of Clinical Trials in the Field of Stem Cell Sciences and Cell Therapy in Asia Pacific Region by 2016. [Source: clinicaltrials.gov.]

D. Some Achievements

MAGSIEVE Separator

Magnetic-activated cell sorting (MACS) is an important method to separate stem cell populations. Until recently, two major companies dominated the production of the technology to perform MACS in the world. However, an Iranian knowledge-based company acquired the technology to produce such equipment and manufacture a device called MAGSIEVE separator, which is as efficient as similar foreign products. The device is meant for clinical use.

• Stem Cell Bone Allografts

A number of Iranian knowledge-based companies produce stem cell bone allografts in different sizes and shapes which are currently used by the hospitals across the country. These structures have orthopaedic applications to treat unhealable broken bones.

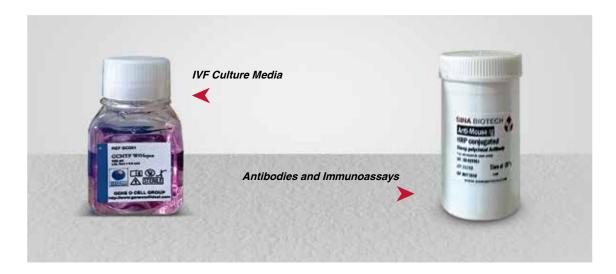


• IVF Culture Media

In Vitro Fertilization (IVF) culture media is produced by a domestic knowledge-based company with numerous applications in fertility clinics. The rising number of infertility cases in the country has increased the demand for this product.

Antibodies and Immunoassays

Different kinds of monoclonal and polyclonal antibodies are domestically produced by a number of companies which have made these products available to the market. These antibodies are highly used in stem cell research for separation and identification kits.



• Polymer Scaffolds

A number of Iranian knowledge-based companies produce synthetic and natural polymer scaffolds in various textures. Stem cell culture and preservation media and buffers are also produced by some domestic companies. Although the raw material for these products is imported, their final production cost is by far less than that of similar foreign products. Moreover, due to short expiration date, these products are continuously produced and supplied to the domestic market.



Electrospun Scaffolds Made of Multiple Fibers including Polycaprolactone (PCL)

IV. Authorities

A. The Council for Stem Cell Sciences and Technologies

As already mentioned, the Council for Stem Cell Sciences and Technologies affiliated to the Vice-Presidency for Science and Technology was established in February 2009 with a view to accelerate the growth of stem cell sciences and technologies in the country to keep pace with other countries in the field. A new team of experts composed of prominent professors, researchers and producers of stem cell sciences in the country was formed in 2005 to provide the infrastructures, devise the comprehensive plan and determine the future goals of this valuable stream of science.

In 2015, numerous measures were taken and implemented in line with the commands stipulated in the comprehensive national document, the most significant of which are as follows:

- Formulating the country's 10-year strategic plan by 2025 in one, five and ten-year subdivisions;
- Absorbing 700 researchers into the council and assigning them to 25 target-oriented expert committees;
- Organizing the biggest national scientific forum in the field of stem cell sciences (the annual festival);
- Setting up associations to develop stem cell sciences and regenerative medicine at provincial universities of medical sciences.

B. Universities

Medical universities across the country are interested in expanding the knowledge related to stem cells in local cities, while research centers affiliated to these universities are in charge of taking care of the research activities. Tehran, Tabriz and Shiraz universities of medical sciences, in collaboration with the Council for Stem Cell Sciences and Technologies, are in the process of establishing a center to conduct research in the field of regenerative medicine. Meanwhile, 19 other medical universities are actively working in the field of stem cell sciences and regenerative medicine. In addition, more than 20 universities affiliated to the Ministry of Science, Research and Technology are cooperating with the universities affiliated to the Ministry of Health and Medical Education in fields such as biomaterials, tissue engineering and manufacturing the equipment for regenerative medicine.

V. International Cooperation

Regarding international cooperation, the Council for Stem Cell Sciences and Technologies is interested in:

- Collaborating with universities, research centers, and companies at the international level to conduct joint clinical trials in stem cell sciences and regenerative medicine;
- Conducting gene therapy studies and clinical trials on genetic disorders such as thalassemia, severe congenital immune deficiencies, etc.;
- Exchanging university professors, students, and experts in the field of cancer cell therapy including CAR T-Cell therapy.