

newsletter

Regenerative medicine

In the field of regenerative medicine - a relatively new branch of biomedicine funded by major international investments - high hopes are being placed on future innovative therapy approaches and curative procedures in the treatment and prevention of diseases which are currently difficult to cure. This is expected to have an impact on the insurance industry.

Introduction

The term "regenerative medicine" (derived from the Latin word "regeneratio") refers to the collaboration between a variety of specialist and research disciplines aimed at throwing light on processes related to cell, tissue and organ functions and developing therapeutic procedures from the knowledge thereby obtained. This may involve some form of biological replacement such as tissue engineering aimed at stimulating the body's own regeneration and repair processes, or individualised medicine, gene and stem cell therapy. A major goal is to counter the manifold problems associated with transplantation medicine (lack of donor organs, organ rejection). The main focus of biomedical research is on the potential of stem cells and tissue engineering. Greater understanding of complex biological regeneration mechanisms goes hand in hand with a huge surge in the possibilities of modern medicine. Some applications (such as artificial organs) are still at the fundamental research stage and will only be feasible in the distant future.

Stem cells

Stem cells constitute the basis for all regenerable tissue and for the development of organs. They can be obtained from the cells of embryos, organs (such as bone marrow), blood or cord blood and used either in autotransplants or allotransplants. Expectations for future cures are particularly high in the fields of cardiac, autoimmune and nervous diseases, chronic inflammatory diseases, solid tumours and bone diseases. The human organism comprises some 220 different cell and tissue types, with stem cells in a category of their own as undifferentiated precursors of all specialised cells. They are capable of unlimited regeneration via division and boast enormous specialisation potential (pluripotency). They multiply either to produce a new pluripotent stem cell or a specialised organ or tissue cell created under the influence of various environmental factors (biological environment). It is not yet entirely clear how this differentiation occurs. Biologists distinguish between two forms of stem cell and categorise them according to their origin and their differentiation potential: embryonic stem cells and adult stem cells.

Embryonic stem cells

Embryonic stem cells are the precursors of all cells of the body. In particular, their pluripotency and potential for unlimited extracorporeal multiplication make them extremely interesting for medical applications in which they are destined to assume the functions of damaged cells. Animal cells are unsuitable for this purpose because of the high likelihood of rejection. The highly complex human organism comprises some 60 billion cells in its entirety and evolves from the fertilised ovum. The cells generated after three divisions are capable of creating an entire organism (totipotency). A few divisions further down the line, they start to specialise and are capable of creating almost all cell types, but no longer an entire organism. Some of

these cells are the embryonic stem cells which constitute the focus of interest for stem cell researchers. They were first cultivated in 1998 and can be further developed into almost all cell types in vitro, thereby paving the way for cell replacement therapy. They can only be harvested by destroying the early embryo. This accounts for the various legal regulations in respect of harvesting, introduction and research which differ from one country to the next, as well as the global debate on ethical and scientific aspects related to the admissibility of stem cell research. The harvesting of embryonic stem cells is prohibited in Germany, while the harvesting of stem cells from animal/human hybrids as well as the harvesting of post-embryonic stem cells from fetuses are hotly disputed topics of debate.

Embryonic stem cells can also be generated via cloning. This involves replacing the genetic material of any ovum with that of a somatic cell and encouraging it to divide. In theory, this practice could be used for every individual to create genetically identical stem cells capable of differentiating into any cell lines (therapeutic cloning). Even the cloning of entire individuals would be theoretically possible (reproductive cloning). Therapeutic cloning is prohibited in Germany, as it is in numerous other countries. Spain and a few other nations permit this form of cloning if certain conditions are met. Initial reports regarding the cloning of a human embryo (in 2004) proved false.

Recent years have seen neonatal stem cells harvested from cord blood and frozen following childbirth in the hope of proving useful in the event of illness. The differentiation potential of these cells is limited (multipotent) according to current knowledge.

Adult stem cells

Most of the tissues and organs are fully developed following birth. Tissue-specific stem cells (adult stem cells) are responsible for the constant reconstruction and repair work that is necessary in the course of a lifetime. Scientists have not yet discovered whether these cells are stored in the tissues or whether they originate elsewhere in the body (such as the bone marrow). Various types of stem cell are found in the tissues, leading to the conclusion that more than one type of stem cell is required for the development of functioning tissues or organs in stem cell therapy. Since every individual possesses adult stem cells, this offers the prospect that these can be replaced by autologous cells in a process known as tissue engineering. Tissue engineering is the cultivation of tissue and cell layers with the aid of biomaterials and growth factors outside the organism. These are subsequently implanted back into the organism for the purpose of reconstruction or the retention of tissue functions. Harvesting can be performed via bone-marrow puncture, from the skin or by means of stem cell apheresis. Autologous stem cells are regarded as an ethically unobjectionable alternative to embryonic stem cells. Some applications, such as skin and cartilage replacements, have already been achieved in clinical practice; problems still remain to be solved before the green light can be given for organ and tissue replacements, however.

Application

Many diseases destroy certain cell types, tissues or organs. Established medical procedures are frequently unable to bring about a cure. Stem cells can be injected intravenously and are assisted by messengers in making their way independently and selectively to the diseased organ. Particular

receptors and enzymes evidently support this selective homing of a defined population of adult stem cells. Current scientific efforts are directed at enhancing the effectiveness of stem cell therapies by means of the mechanisms identified to date. Even though the principles of stem cell transplantation have been applied successfully for over 40 years (to treat diseases such as forms of leukaemia and lymphoma, as well as in animal experiments), it cannot yet be predicted when patients will be able to benefit from them as a matter of routine. The creation or growing of entire replacement organs or limbs remains a vision for the future.

Information for the underwriter

Increased life expectancy has resulted in a continuous rise in the elderly population, which in turn goes hand in hand with a greater need for treatments for diseases related to the failure of cell, tissue and organ functions. These include economically significant conditions such as Alzheimers, diabetes, cardiovascular diseases, hepatic or renal failure, rheumatic diseases, wounds that refuse to heal, accidental and sporting injuries and intervertebral disc degeneration. Added to these are the effects of a lack of exercise and obesity, as well as excessive exertions in the field of competitive sports, such as symptoms of attrition and degeneration (of the joints, for example). Regenerative medicine boasts enormous scientific potential and also has aspirations towards commercialisation. It is thus hardly surprising that companies specialising in this field are handling numerous project and product pipelines. Additionally, it is expected that providers of other substitutes (such as degradable biomaterials and implants), medical engineering and pharmaceutical companies will also become active in the field of regenerative medicine.

Risks

It is currently difficult to predict what the risks of any widespread future application will be (tumour formation following stem cell therapies, rejection etc.). Further difficulties may arise as a result of confusion in respect of the international regulations on product licensing. Other problems could be encountered in respect of classification, as tissue engineering products can be regarded both as medical devices (due to their carrier materials, for example) and as medication owing to their therapeutically active cells and growth factors. These aspects together with extension of the product range must be taken as a basis for risk assessment in respect of product liability covers. Companies are expected to have to conduct more studies on product efficiency and cost-effectiveness than in the past, which could have a knock-on effect on proband liability. The foreseeable rise in the diversity of products used to treat musculoskeletal (particularly articular cartilage) and cardiovascular diseases and in the field of wound treatment and skin replacement (which is expected to record significant growth) could also increasingly affect the health insurance business.

Contact

AssTech GmbH
Postfach 1211
85766 Unterföhring bei München
Telephone + 49 89 3844-1585
Telefax + 49 89 3844-1586
info@asstech.com
www.asstech.com