

REGENERATION CELL THERAPY FOR THE MYOCARDIAL INFARCTION PERCUTANEOUS APPLICATION: FB-1001

Description and pathology

Implant of Autologous Myoblasts (from adult stem cells) in patients with old myocardial damage.

In the myocardial infarction (MI) part of the heart cells necrose and lose their functional capacity, that is, their capacity to contract and pump blood to the tissues.

The cardiac muscle can't be regenerated; as a result, necrosed regions become a fiberlike scar. Depending on the area affected and the capacity of ventricular remodelation, the infarction can lead to a progressive and irreversible decrease of the cardiac function that ends in a congestive heart failure.

Currently, the only one real resource for treating these patients is a cardiac transplant, a very limited procedure, due to the differences between the number of potential donors and the recipients.

There are compromised cells located behind the basal membrane in the skeletal muscle, with the capacity to regenerate the muscle fibres, known as myoblasts or satellite cells.

The technique used is based on the possibility of individual muscle cells (myoblasts) to become muscular fibres able to produce a cardiac work (cellular cardiomyoplasty).

Indications

Regeneration of heart muscle after an old myocardial infarction.

Product

Autologous myoblasts cell suspension, obtained through dissection of a muscular biopsy from the patients.

The culture media has been developed just using autologous human serum obtained with plasmapheresis.

This cell suspension may be implanted in the damaged heart by two different applications: percutaneous or surgical application.

Phase II Clinical Trial

Currently, a Phase II Clinical Trial is being developed in 50 patients (25 patients vs 25 controls) that suffered old myocardial infarction, with the goal of comparing the improvement in the global and the regional cardiac function in patients with old myocardial infarction obtained through percutaneous application of autologous myoblasts.

The final data of this study will be available in the second semester of 2013, but the professionals involved in this research show great confidence in positive results.

Publications

1. Gavira J.J. et al. "A comparison between percutaneous and surgical transplantation of autologous skeletal myoblast in a swine model of chronic myocardial infarction". Cardiovascular Research (2006).
2. Herreros J. et al. "Autologous intramyocardial injection of cultured skeletal muscle-derived stem cells in patients with non-acute myocardial infarction". European Heart Journal (2003).

Intellectual property

- Spanish Patent granted on 28th March 2005: 200201540.
- European patent pending: (Priority Date: 2nd July 2002).
- Patent granted in Australia, Mexico, India, South Korea, China, Russia and New Zealand.
- Patent pending in Brazil, USA, Japan and Israel.

