

Method of treating pancreatic and liver conditions by endoscopic-mediated (or laparoscopic-mediated) transplantation of stem cells into/onto bile duct walls of a particular region of the biliary tree.

KEYWORDS

□ REGENERATIVE MEDICINE

□ STEM CELLS

□ CELL THERAPY

□ DIABETES MELLITUS

□ LIVER CIRRHOSIS

AREA

□ PHARMACEUTICAL

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Patent Type

Patent for invention.

Co-Ownership

Sapienza University of Rome 33%,
University of North Carolina at Chapel Hill 33%,
Diabetes Research Institute at Miami (FL) 33%.

Inventors

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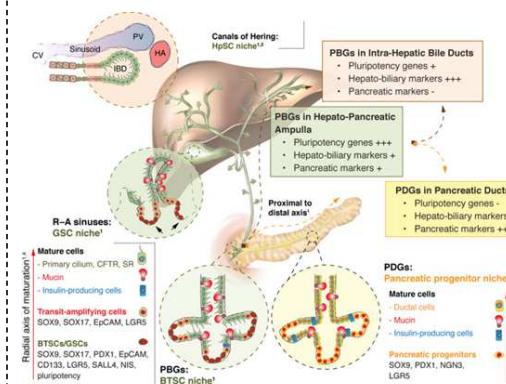
Industrial & Commercial Reference

Sector pharmaceutical, biotechnological
and of personalized medicine.

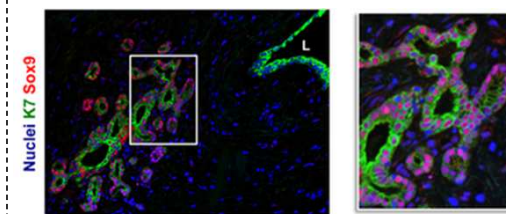
Time to Market

A phase I / II clinical trial of cell therapy
with biliary tree stem cells is underway,
demonstrating an advanced state of
experimentation.

LICENSED



from: Alvaro D, Gaudio E.
Hepatology 2016; 64(2):644.



from: Lanzoni G, Cardinale V, Carpino G.
Hepatology 2015; 64(1):277-286.

Abstract

A method of repairing diseased or dysfunctional pancreas or liver based on the preparation of a suspension of stem cells and/or progenitor cells such as biliary tree stem cells, hepatic stem cells, pancreatic stem cells or their descendants, committed progenitor cells, from healthy tissue of the patient or of the biliary tree of a non-autologous donor and engrafting the cells into the wall of bile ducts near to the organ to be treated. The graft consists of stem cells or progenitors that are admixed with biomaterials and, optionally, with cytokines and/or native epithelial-mesenchymal cells. The cells are specifically introduced to the hepato-pancreatic common duct.

Publications

- ❖ Carpino G, Cardinale V, Gentile R, Onori P, Semeraro R, Franchitto A, Wang Y, Bosco D, Iossa A, Napoletano C, Cantafora A, D'Argenio G, Nuti M, Caporaso N, Berloco P, Venere R, Oikawa T, Reid L, Alvaro D, Gaudio E. J Hepatol. Evidence for multipotent endodermal stem/progenitor cell populations in human gallbladder. 2014 Jun. 60(6):1194-202.
- ❖ Carpino G, Cardinale V, Gaudio E, Alvaro D, et al. Hyaluronan coating improves liver engraftment of transplanted human biliary tree stem/progenitor cells. Stem Cell Res Ther. 2017 Mar 20;8(1):68. doi: 10.1186/s13287-017-0492-7.



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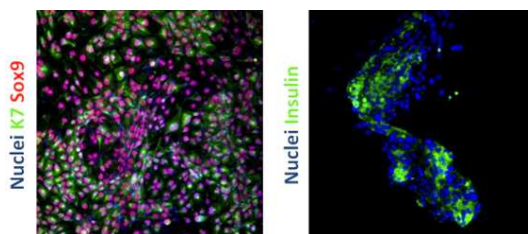
Method of treating pancreatic and liver conditions by endoscopic-mediated (or laparoscopic-mediated) transplantation of stem cells into/onto bile duct walls of a particular region of the biliary tree.

Technical Description

This invention provides a method for the delivery of any stem cell population by direct injection or by grafting strategies to the reservoir of stem cell niches giving rise to liver and pancreas, without physically disturbing or compromising the physical integrity of these organs.

The method comprises:

(a) obtaining a suspension of the stem cells or their descendants, committed progenitor cells, respectively; and (b) introducing the suspension into or onto the walls of the hepato-pancreatic common duct - in the case of pancreas - or the walls of the biliary tree near the liver - in the case of liver, wherein a substantial portion of the cells takes residence in the wall, and wherein the cells mature into functional pancreatic or liver cells and migrate to the pancreas or liver.



from: Carpino G et al.
Stem Cells 2016; 34(5):1332-42.

Technologies & Advantages

Treatment of advanced liver diseases and diabetes lacks healing therapies, with the exception of liver and pancreas transplantation, which are not risk-free and lead to life-long immunosuppressive therapy for the affected patient.

The technical advantages associated with the use of this invention lie in preserving the integrity of the organism using the recipient's biliary tree as a support for the stem cell population or progenitor population.

The technique used to transplant cells through the pre-existing path in this invention is endoscopic or echoendoscopic.

This technique is not invasive and is possible in all patients even if seriously compromised, or with alteration of the coagulation, conditions that affect any surgical intervention.

Through this method of transplantation it is possible to obtain the engraftment within the physiological stem niches of the biliary tree that constitute an anatomical network that connects these niches with the liver and pancreas stem niches, thus allowing the cells to be inside the regenerative compartments of the respective organs.

Finally, the stem / progenitor cells of the biliary tree are a physiological source of mature cells of the liver and pancreas and do not require any immuno-suppressive therapy to avoid their rejection due to their ability to immunomodulate.

Applications

Regenerative medicine has entered a new phase in which stem cell populations are being transplanted into patients to restore damaged or diseased tissues such as liver and pancreas.

Liver diseases, potentially leading to organ failure due to hepatitis viruses, alcohol consumption, diet and metabolic disorders, and other causes, constitute a major medical burden world-wide.

Similarly, pancreatic diseases, particularly diabetes, are a leading cause of health problems and death world-wide. Stem/progenitor cell therapies represent possible approaches to address these needs for treatment, and clinical programs are expanding worldwide to further explore these novel therapies.

Although many types of precursors are being tested for clinical programs treating liver and pancreas, only certain ones are feasible for clinical programs in near future.

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