

Cryopreservation Method.

KEYWORDS

- ☐ REGENERATIVE MEDICINE
- ☐ CRYO-PRESERVATION
- ☐ VIABILITY
- ☐ STEM CELLS
- ☐ CELL THERAPY
- ☐ DIABETES MELLITUS
- ☐ LIVER CIRRHOSIS

AREA

- ☐ PHARMACEUTICAL

CONTACTS

➤ PHONE NUMBERS
+39.06.49910888
+39.06.49910855

➤ EMAIL
u_brevetti@uniroma1.it

Priority Number

U.S. Application 62/482644 (Provisional)
_ 06.04.2017.

Patent Type

Patent for invention.

Co-Ownership

Sapienza University of Rome 50%,
University of North Carolina 50%.

Inventors

Domenico Alvaro, Eugenio Gaudio,
Guido Carpino, Lola M. Reid, Vincenzo
Cardinale.

Industrial & Commercial Reference

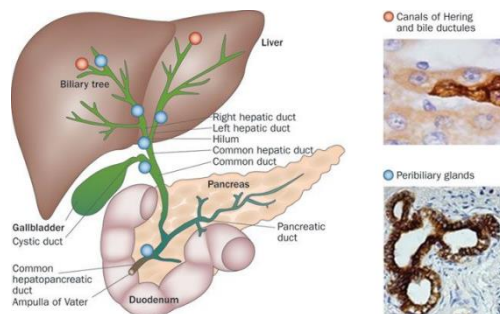
Sector pharmaceutical, biotechnological
and of personalized medicine.

Time to Market

The method and the materials used do
not involve manipulation and therefore
the cryopreserved stem cells can be used
in clinical programs.

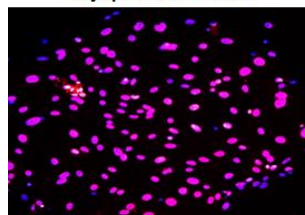
Availability

Cession, Licensing, Research, Develop-
ment, Experimentation, Collaboration,
Start-up and Spin-off.



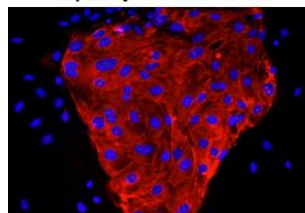
from: Cardinale V et al.
Nat Rev Gastroenterol Hepatol 2012; 9: 231–240.

Cryopreserved BTSC



Nuclei Sox9

Hepatocyte Differentiation



Nuclei Albumin

from: Nevi L et al.
Sci Rep. 2017;7(1):6080.

Abstract

Aspects of the present invention relate to a method for cryopreservation of human biliary tree stem/progenitor cells comprising collecting and adding a cryopreservation solution to the cells, in which the cryopreservation solution comprises (a) a basal medium comprising lipids, (b) hyaluronans (HA), (c) a cryoprotectant, (d) an antioxidant, and a serum replacement factor, optionally albumin; and (e) cooling the cells from an initial temperature to a final temperature at which the cells are frozen remaining highly viable.

The method does not involve manipulation and the materials used are approved for clinical use and therefore the cryopreserved stem cells can be used in clinical programs.

Publications

- ❖ Semeraro R, Carpino G, Cardinale V, Onori P, Gentile R, Cantafora A, Franchitto A, Napoli C, Anceschi M, Brunelli R, Bosco D, Torrice A, Reid L, Gaudio E, Alvaro D. J Hepatol. Multipotent stem/progenitor cells in the human foetal biliary tree. 2012 Nov. 57(5):987-94. doi: 10.1016/j.jhep.2012.07.013.
- ❖ Carpino G, Cardinale V, Alvaro D, Gaudio E, et al. HepatolHuman biliary tree stem/progenitor cells immunomodulation: Role of hepatocyte growth factor. Res. 2017 Apr;47(5):465-479. doi: 10.1111/hepr.12772.



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Cryopreservation Method.

Technical Description

Biliary tree stem cells are capable of differentiating into hepatic, biliary and pancreatic cells.

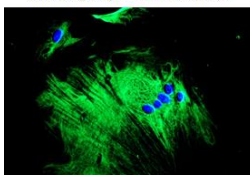
Their clinical use needs efforts to improve the logistics.

This invention allows cells to be stored for months, for example, while waiting for a needy patient, and therefore to be able to dispose of cells with the same characteristics of freshly isolated cells at any time, which are only available in the presence of a donor.

In particular, after freezing / thawing, the biliary tree stem cells maintain a high vitality, proliferation, multipotentiality, and a high capacity for engraftment in vivo.

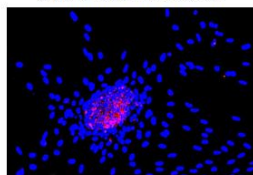
This result was made possible thanks to the innovative composition of the freezing solution, which is also based on GMP materials already approved for clinical use.

Cholangiocyte Differentiation



Nuclei CK19

β -pancreatic differentiation



Nuclei Insulin

from:

Nevi L et al. Sci Rep. 2017;7(1):6080.

Technologies & Advantages

Treatment of advanced liver diseases and diabetes lacks of effective therapies, with the exception of liver or pancreas transplantation, respectively, which are not free of risks, and involve for the patient affected the immunosuppressive therapy for the entire lifespan.

Stem cells / progenitors of the biliary tree are a physiological source of mature cells of the liver and pancreas, and do not require any immunosuppressive therapy. Furthermore, therapy with such cells is potentially autologous.

Their cryopreservation allows to preserve the cells for months, for example, waiting for a needy patient, and therefore to be able to dispose of cells with the same characteristics of the freshly isolated ones, which are available only in the presence of a donor. The method does not involve manipulations and the materials used are approved for clinical use and therefore the cryopreserved stem cells can be used in clinical programs.

This leads to a huge gain in terms of time and resources to achieve the clinical application, moreover make the cells always available and the therapy can be scheduled (Day-Hospital).

Applications

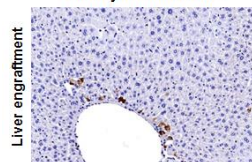
Regenerative medicine has entered a new phase in which stem cell populations are being transplanted into patients to restore damaged or diseased tissues such as liver and pancreas.

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.

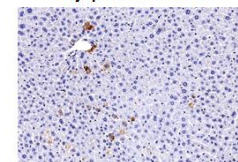
Although many types of precursors are being tested for clinical programs treating liver and pancreas, only certain ones are feasible for clinical programs in near future.

Freshly isolated BTSCs



Liver engraftment

Cryopreserved BTSCs



from:

Nevi L et al. Sci Rep. 2017;7(1):6080.

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