



Florida Integrative Medical Center
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RGCC iPSC's (CD34)

Disclaimer for iPSC (CD34)

1. iPSC is a biological drug.

Biological drugs often represent the cutting-edge of biomedical research and, in time, may offer the most effective means to treat a variety of medical illnesses and conditions that presently have no other treatments available.

Therefore, the Public Health Service Act (PHSA) provides special regulatory requirements for marketing traditional biologics and human cell products.

Biologics are regulated under Section 361 of PHS Act. Under the section 361 regulation for biological drugs, it is not required to obtain premarket approval/clearance from the FDA, if they meet the following requirements.

Biologics are minimally manipulated. They are intended for autologous use only, that means from an individual patient back to the same patient.

Do not involve the combination of the cells with other articles.

Does not have a systemic effect and are not dependent upon the metabolic activity of living cells for its function.

2. Biological drugs from the European Union (EU)

The European Medical Agency (EMA) and the FDA have signed an agreement on mutual recognition of inspections between European Community and the United States on 1 November 2017. (A similar agreement between EU and US existed since 1998 but was never fully implemented).

FDA confirmed on 1 November 2017 the capability, capacity, and procedures in place to carry out good manufacturing practice (GMP) inspections of the EU members, among others Greece.

That means that US regulators rely on each other's GMP inspection reports issued by a recognized authority for manufacturing facilities located outside their respective territories (see Article 3 (1) of the GMP Sectoral Annex MRA).

GENERAL DISCUSSION OF iPSC's REGARDING USE AND PREPARATION

The correct explanation used for "reprogramming" of iPSCs is as follows:

RGCC applies transient micro-RNA to switch off the temporary genes that will lead to terminal differentiation and this leads to less differentiated cells which are called totipotent (to-ti-po-tent) iPSCs. These can give rise to any cell type in the human body.

These are not originated from embryos, but from each individual we take blood from and therefore are NOT embryonic iPSCs. However, despite this fact from a phenotyping and functionality point of view they are the same.

Quality control is performed on every step of the process until the final product is ready and safe for use. QC involves monitoring the cell culture for microbial contamination, and the cells themselves for specific marker expression. You will also receive a certificate of sterility with your cells.

RGCC guarantees the cells have had no genetic (DNA) tampering whatsoever and will have a document of sterility accompany each sample. RGCC are hopeful we'll also be given the actual number of iPSC's received for each person.

CD34 cells (AKA induced pluripotent stem cells- iPSCs) are hematopoietic stem cells. Their role is to give rise to other blood cell types. They are normally found in the bone marrow of (pelvis, femur, sternum), umbilical cord blood and peripheral blood. They are quiescent in nature which gives them the ability to survive in the hypoxic environment of the tissues they reside in. However, when they are "woken up", they will have a high self-renewal capacity, multipotency and increased mobility.

(CD34 cells) AKA iPSC's have no anticancer effects. However, in many studies they have been used in combination with chemo (Mega Therapy) or as an adjuvant arm in immunotherapy. Their use is to replace damaged tissue. ONLY GENETICALLY ENGINEERED iPSCs HAVE ANTICANCER EFFECT BUT THEY ARE NOT ALLOWED TO BE USED IN THE CLINICAL FIELD!

Example uses: Solid tumors, autoimmune diseases, non-hematopoietic and hematopoietic congenital disorders; AML, CML, ALL, Hodgkin's, non-Hodgkin's Lymphoma, neuroblastomas, Ewing's Sarcoma, Multiple Myeloma, myelodysplastic syndromes and glioma. In non-cancerous disorders they can be used in thalassemia, sickle cell anemia, aplastic anemia, Fanconi anemia, immune deficiency syndromes and autoimmune diseases.

The CD34 cells work because from them one may get several lines of differentiation by reprogramming. Hence, they can be used for more than one tissue type.

R.G.C.C., S.A. uses magnetic beads and FACS (Fluorescence Activated Cell Sorting) isolation methods to identify and isolate CD34 cells from peripheral blood. Cells are then cultivated with media and supplements that induce greatly the proliferation of the hematopoietic stem cells. Once their number is adequate, they are either sent directly to the patients' doctor for infusion or can be kept in LN (Liquid Nitrogen) tanks until requested, (CD34 cells can be kept for 5 years). Reconstitution from LN needs to take place very fast (in just a few minutes) so that the loss will only be around 2.5 to 3%. This procedure is very well known by those already using autologous transplantation. After the administration it is possible to experience fever. NSAID is safe to take if need be and report to our office.

I request the members and healthcare providers at Florida Integrative Medical Center to administer the iPCs treatment to me.

Patient name (Print) _____ Date: _____

Patient Signature: _____

Witness Name: _____ Date: _____

Witness Signature: _____