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info@actabioethica.cl
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THERAPEUTIC USE OF HUMAN EMBRYONIC STEM CELLS

Justo Aznar[1], Pedro Navarro-Illana[2]

Human embryonic stem cells (hESC) are pluripotent cells derived from the blastocyst inner cell mass, a 5-6 day-old embryo. In order to obtain these cells, that early human embryo needs to be destroyed, causing objective ethical problems.

The first hESC lines were produced by Thomson et al. in 1998*(1)*. Since, they have been widely used for experimental purposes; however, their therapeutic use is much more reduced.

In fact, ClinicalTrials.org states that 144,300 clinical trials have been carried out worldwide*(2)*. 4451 of those, with adult stem cells, and only 15 with hESC (Table 1).

Table 1. Clinical trials now under way about human embryonic stem cells. According to the website clinicaltrials.org (accessed in October 28, 2013).

Nº	Status	Trial
1	Not yet recruiting	A Study Of Implantation Of Human Embryonic Stem Cell Derived Retinal Pigment Epithelium In Subjects With Acute Wet Age Related MacularDegeneration And Recent Rapid Vision Decline.
2	Recruiting	A Phase I/IIa, Open-Label, Single-Center, Prospective Study to Determine the Safety and Tolerability of Sub-retinal Transplantation of Human Embryonic Stem Cell Derived Retinal Pigmented Epithelial (MA09-hRPE) Cells in Patients With Advanced Dry Age-related Macular Degeneration (AMD).
3	Recruiting	Safety and Tolerability of Sub-retinal Transplantation of Human Embryonic Stem Cell Derived Retinal Pigmented Epithelial (hESC-RPE) Cells in Patients With Stargardt's Macular Dystrophy (SMD).
4	Recruiting	The Derivation of Human Embryonic Stem Cell Lines From PGD Embryos.
5	Recruiting	Safety and Tolerability of Sub-retinal Transplantation of hESC Derived RPE (MA09-hRPE) Cells in Patients With Advanced Dry Age Related Macular Degeneration.
6	Recruiting	Derivation of New Human Embryonic Stem Cell Lines Lines for Clinical Use.
7	Recruiting	Sub-retinal Transplantation of hESC Derived RPE (MA09-hRPE) Cells in Patients With Stargardt's Macular Dystrophy.
8	Recruiting	Safety and Tolerability of MA09-hRPE Cells in Patients With Stargardt's Macular Dystrophy (SMD).
9	Unknown †	Derivation of New Human Embryonic Stem Cell Lines: Identification of Instructive Factors for Germ Cells Development.
10	Active, not recruiting	Development of iPS From Donated Somatic Cells of Patients With Neurological Diseases.
11	Completed	The Transendocardial Autologous Cells (hMSC or hBMC) in Ischemic Heart Failure Trial (TAC-HFT).

[1] Director of the Institute of Life Sciences, Catholic University of Valencia,Valencia, Spain
Correspondence: justo.aznar@ucv.es

[2] Dean of Nursing Faculty. Catholic University of Valencia "San Vicente Mártir", Valencia, Spain

12	Terminated	Skin and Blood Research Samples From Healthy Volunteers and Patients With Hematologic Diseases.
13	Completed	The Percutaneous Stem Cell Injection Delivery Effects on Neomyogenesis Pilot Study (The POSEIDON-Pilot Study).
14	Recruiting	Stem Cell Educator Therapy in Type 1 Diabetes.
15	Active, not recruiting	Evaluation of Circulating Levels of Adult Stem Cells in the Peripheral Blood of Patients With Acute Decompensated Heart Failure and Following Stabilization, in Comparison With Healthy Volunteers.

In order to ascertain that those 15 clinical trials had actually used hESC with therapeutic purposes, we analyzed them to see whether there was objective data.

We previously established that the aim of trials 10 and 12 was to produce induced pluripotent stem cells (iPS) or to assess their action. In trial 13, they used autologous mesenchymal cells; in trial 14, umbilical cord cells and, in trial 15, only adult stem cells circulating levels were assessed.

In trials 1 and 9, hESC were used, however in trial 1 there had not been patient recruitment yet. In trial 2, the first data would not be obtained until February 2016; in trial 3 until January 2014 and, in trial 8, until August 2014. Clinical trials 4, 6 and 9 were aimed at improving the obtaining technique of the embryonic stem cells lines.

Only trials 5 and 7 had the objective to assess the hESC therapeutic use and provided a specific result.

Preliminary data of these two trials has been published in The Lancet*(3)*. In trial 5 (NCT01345006), they assessed the safety and tolerability of retinal transplantation of hESC-derived retinal pigmented epithelium (hESCP-RPE) on a patient with Stargardt macular dystrophy and on a patient with dry age-related macular degeneration, in trial 7 (NCT 01344993). The visual acuity improved from hand motions to 20/800 in the eye study of the patient with Stargardt macular dystrophy and vision also seemed to improve in the patient with dry age-related macular degeneration (from 21 ETDRS letters to 28).

Thus, can anything be concluded from the use of hESC for therapeutic purposes only from the data of these two patients? In our opinion, there is no medical evidence that justifies their use.

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