ClinicalTrials.gov

Trial record **1 of 1** for: NCT01056471

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Autologous Mesenchymal Stem Cells From Adipose Tissue in Patients With Secondary Progressive Multiple Sclerosis

This study has been completed.

Sponsor:
Andalusian Initiative for Advanced Therapies - Fundación Pública Andaluza Progreso y Salud

Collaborator:
Carlos III Health Institute

Information provided by (Responsible Party):
Andalusian Initiative for Advanced Therapies - Fundación Pública Andaluza Progreso y Salud

ClinicalTrials.gov Identifier:
NCT01056471

First received: January 25, 2010
Last updated: August 4, 2015
Last verified: February 2015
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Tracking Information	
First Received Date ICMJE	January 25, 2010
Last Updated Date	August 4, 2015
Start Date ICMJE	January 2010
Primary Completion Date	June 2012 (Final data collection date for primary outcome measure)
Current Primary Outcome Measures ICMJE **(submitted: April 23, 2010)**	To evaluate safety and tolerability related to the intravenous infusion of autologous mesenchymal stem cells [Time Frame: 12 months.]
Original Primary Outcome Measures ICMJE **(submitted: January 25, 2010)**	To evaluate safety and tolerability related to the intravenous infusion of autologous mesenchymal stem cells [Time Frame: 24 hr, 8 days, 1, 2, 3, 6, 9 and 12 months.]
Change History	Complete list of historical versions of study NCT01056471 on ClinicalTrials.gov Archive Site
Current Secondary Outcome Measures ICMJE **(submitted: April 23, 2010)**	To evaluate effects on MS disease activity measured by: clinical variables, imaging variables, immunological and neurophysiologic analysis, neuropsychological and quality of life scales. [Time Frame: 12 months]
Original Secondary Outcome Measures ICMJE **(submitted: January 25, 2010)**	To evaluate effects on MS disease activity measured by: clinical variables, imaging variables, immunological and neurophysiologic analysis, neuropsychological and quality of life scales. [Time Frame: 24 hr, 8 days, 1, 2, 3, 6, 9 and 12 months]
Current Other Outcome Measures ICMJE	*Not Provided*
Original Other Outcome Measures ICMJE	*Not Provided*

Descriptive Information

Brief Title ICMJE	Autologous Mesenchymal Stem Cells From Adipose Tissue in Patients With Secondary Progressive Multiple Sclerosis
Official Title ICMJE	Multicenter Clinical Trial Phase I / II Randomized, Placebo-controlled Study to Evaluate Safety and Feasibility of Therapy With Two Different Doses of Autologous Mesenchymal Stem Cells in Patients With Secondary Progressive Multiple Sclerosis Who do Not Respond to Treatment
Brief Summary	The main purpose of this study is to evaluate the safety and feasibility of regenerative therapy with mesenchymal stem cells from adipose tissue, administered intravenously in patients with secondary progressive multiple sclerosis who do not respond to treatment.
Detailed Description	*Not Provided*
Study Type ICMJE	Interventional
Study Phase	Phase 1 Phase 2
Study Design ICMJE	Allocation: Randomized Intervention Model: Parallel Assignment Masking: Double Blind (Participant, Care Provider, Investigator, Outcomes Assessor) Primary Purpose: Treatment
Condition ICMJE	• Autoimmune Diseases • Immune System Diseases • Demyelinating Diseases • Nervous System Diseases • Demyelinating Autoimmune Diseases, CNS • Autoimmune Diseases of the Nervous System
Intervention ICMJE	• Other: Autologous mesenchymal stem cells from adipose tissue. Intravenous infusion of autologous mesenchymal stem cells.Dose:4*10e6 cells/Kg. • Other: Autologous mesenchymal stem cells from adipose tissue. Intravenous infusion of autologous mesenchymal stem cells. Dose: 10e6 cells/Kg.
Study Arms	• Experimental: Low dose autologous mesenchymal cells The dose of infused cells is 10e6 cells/Kg Intervention: Other: Autologous mesenchymal stem cells from adipose tissue. • Experimental: High dose The dose of infused cells is 4*10e6 cells/Kg Intervention: Other: Autologous mesenchymal stem cells from adipose tissue. • No Intervention: Placebo Control
Publications *	*Not Provided*

*** Includes publications given by the data provider as well as publications identified by ClinicalTrials.gov Identifier (NCT Number) in Medline.**

Recruitment Information

Recruitment Status ICMJE	Completed
Enrollment ICMJE	30
Completion Date	June 2015
Primary Completion Date	June 2012 (Final data collection date for primary outcome measure)
Eligibility Criteria ICMJE	Inclusion Criteria: 1. Patients diagnosed with Multiple Sclerosis (Poser and McDonald criteria). 2. Secondary progressive MS patients with EDSS ≥ 5.5 and ≤ 9.

	3. Patients with treatment failure defined by: no response to immunomodulators / immunosuppressants, and showing activity in the form of 1 relapse in the last year or 0.5 points in EDSS progression. 4. Patients with no MS relapse and no steroid treatment within the month prior to inclusion. 5. Patients who give written consent to participate in the study. - Exclusion Criteria: 1. History of current pathology or current laboratory results indicative of any severe disease. 2. Pacemaker or metallic implants that prevent MR imaging. 3. Inability to complete questionnaires. 4. Refusal to give informed consent. 5. Predicted impossibility for a biopsy of at least 30 grams of fat tissue. 6. Positive screening test for HIV, Hepatitis B or Hepatitis C. 7. History of malignancy. 8. Having been in treatment with any investigational drug or have undergone any experimental procedure in the 3 months prior to baseline. 9. Body mass index> 40 kg/m2. 10. Patients who have been treated with prohibited concomitant medication during the month prior to inclusion in the study. 11. Pregnancy or lactation
Sex/Gender	Sexes Eligible for Study: All
Ages	18 Years and older (Adult, Senior)
Accepts Healthy Volunteers	No
Contacts ICMJE	*Contact information is only displayed when the study is recruiting subjects*
Listed Location Countries ICMJE	Spain
Removed Location Countries	

Administrative Information

NCT Number ICMJE	NCT01056471
Other Study ID Numbers ICMJE	CMM/EM/2008
Has Data Monitoring Committee	No
U.S. FDA-regulated Product	*Not Provided*
Plan to Share Data	*Not Provided*
IPD Description	*Not Provided*
Responsible Party	Andalusian Initiative for Advanced Therapies - Fundación Pública Andaluza Progreso y Salud
Study Sponsor ICMJE	Andalusian Initiative for Advanced Therapies - Fundación Pública Andaluza Progreso y Salud
Collaborators ICMJE	Carlos III Health Institute
Investigators ICMJE	Study Director: Oscar Fernandez Fernandez, MD, PhD — Hospital Regional Universitario Carlos Haya, Málaga, Spain. Principal Investigator: Guillermo Izquierdo Ayuso, MD, PhD — Hospital Universitario Virgen Macarena, Sevilla, Spain
Information Provided By	Andalusian Initiative for Advanced Therapies - Fundación Pública Andaluza Progreso y Salud
Verification Date	February 2015

ICMJE **Data element required by the International Committee of Medical Journal Editors and the World Health Organization ICTRP**