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

Purpose

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.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Autoimmune Diseases</td>
<td>Other: Autologous mesenchymal stem cells from adipose tissue.</td>
<td>Phase 1</td>
</tr>
<tr>
<td>Immune System Diseases</td>
<td></td>
<td>Phase 2</td>
</tr>
<tr>
<td>Demyelinating Diseases</td>
<td></td>
<td></td>
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<tr>
<td>Nervous System Diseases</td>
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<tr>
<td>Demyelinating Autoimmune Diseases, CNS</td>
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<tr>
<td>Autoimmune Diseases of the Nervous System</td>
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</tbody>
</table>

Study Type: Intervenional
Study Design: Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: Double Blind (Participant, Care Provider, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: 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

Resource links provided by NLM:
- Genetics Home Reference related topics: multiple sclerosis
- MedlinePlus related topics: Multiple Sclerosis
- U.S. FDA Resources
Further study details as provided by Andalusian Initiative for Advanced Therapies - Fundación Pública Andaluza Progreso y Salud:

Primary Outcome Measures:
- To evaluate safety and tolerability related to the intravenous infusion of autologous mesenchymal stem cells [Time Frame: 12 months.]

Secondary Outcome Measures:
- 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]

Enrollment: 30
Study Start Date: January 2010
Study Completion Date: June 2015
Primary Completion Date: June 2012 (Final data collection date for primary outcome measure)

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental: Low dose autologous mesenchymal cells</td>
<td>Other: Autologous mesenchymal stem cells from adipose tissue. Intravenous infusion of autologous mesenchymal stem cells. Dose: 10e6 cells/Kg.</td>
</tr>
<tr>
<td>The dose of infused cells is 10e6 cells/Kg</td>
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</tr>
<tr>
<td>Experimental: High dose</td>
<td>Other: Autologous mesenchymal stem cells from adipose tissue. Intravenous infusion of autologous mesenchymal stem cells. Dose: 4*10e6 cells/Kg.</td>
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<tr>
<td>The dose of infused cells is 4*10e6 cells/Kg</td>
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<tr>
<td>No Intervention: Placebo Control</td>
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</tbody>
</table>

Eligibility

Ages Eligible for Study: 18 Years and older (Adult, Senior)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No

Criteria

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

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

https://www.clinicaltrials.gov/ct2/show/study/NCT01056471?term=NC...
Autologous Mesenchymal Stem Cells From Adipose Tissue in Patients...