Clinical Trial Details (PDF Generation Date :- Sat, 17 Jan 2015 21:57:24 GMT)

CTRI Number	CTRI/2014/11/005231 [Registered on: 28/11/2014] - **Trial Registered Prospectively**
Last Modified On	28/11/2014
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Stem Cell Therapy
Study Design	Single Arm Trial
Public Title of Study	Stem Cell injection in Multiple Sclerosis patients
Scientific Title of Study	Study of Safety, Feasibility and Efficacy of Autologous Mesenchymal Stem Cells in Multiple Sclerosis

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr Rohit Bhatia
Designation	Additional Professor
Affiliation	All India Institute of Medical Sciences
Address	Room no 603, department of neurology ansari nagar delhi 110029 South West DELHI 110029 India
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Details Contact Person (Scientific Query)

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Name	Dr Rohit Bhatia
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Source of Monetary or Material Support

Source of Monetary or Material Support
> Applied to Department of Biotechnology

Primary Sponsor

Primary Sponsor Details	
Name	Department of Biotechnology
Address	Department of Biotechnology 6th-8th Floor, Block 2 CGO Complex, Lodhi Road New Delhi - 110 003 India
Type of Sponsor	Government funding agency

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Rohit Bhatia	All india institute of medical sciences	ROOM NO 603 , Department of Neurology Ansari nagar South West DELHI	01126546625 rohitbhatia71@yahoo.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional Committee for Stem Cell Research (IC-SCRT)	Approved	14/08/2014	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Multiple Sclerosis

Intervention / Comparator Agent

Type	Name	Details
Intervention	Mesenchymal stem cells	Culturing of cells would approximately take 3 weeks which will be a sterile procedure in GMP certified lab.There is no manipulation done in culturing the cells and will be done according to the GMP certified SOPs 1-2 million /kg body weight cells will be dissolved in 200 ml saline and infused intravenously over 3-4 hours. This will be single dose.
Comparator Agent	standard care	standard drug regime

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	50.00 Year(s)
Gender	Both
Details	Clinically definite MS based on Revised McDonald's criteria. Relapsing Remitting MS: a. Patients who have a fixed EDSS of 4 (not during a relapse) b. Unresponsive to one or more approved first or second line therapies (interferons, glatiramer acetate, natalizumab, mitoxantrone, methotrexate, azathioprine for more than one year defined as:

	more than 2 relapses in the preceding one year of therapy. Persisting enhancement on MRI done within last one year. 1 point increase in EDSS over one year. c. Failure or Intolerance to first line DMTs (interferon beta and glatiramer acetate). d. Inability to afford DMT and failure to respond to oral immunosuppressive therapy with methotrexate and azathioprine. Secondary Progressive MS not responding to approved therapy and evidenced by progression of the disease with moderate to severe relapse with an increase of EDSS of 1 point if baseline EDSS less than 5 Or 0.5 points if baseline EDSS more than 5 at baseline within a year; and or worsening MRI lesion load (equal to 2 enhancing lesions in the last 12 months. Primary Progressive MS: 6 months to one year of active disease progression as documented by worsening EDSS of of 1 point if baseline EDSS less than or equal to 5 OR 0.5 points if baseline EDSS is more than 5 at baseline within a year Expanded disability status scale (EDSS) score of between 3-7 at screening evaluation. Able to give written informed consent.

Exclusion Criteria

Exclusion Criteria	
Details	active infection immunocompromised states neoplastic diseases history or laboratory results indicative of any significant cardiac, endocrinological metabolic hematologic and immunologic diseases. Patients who have received natalizumab or fingolimod within last 3 months Patients who had received glatiramer acetate orinterferons within last two months Female patients with known pregnancy or at risk of being pregnant

Method of Generating Random Sequence	Not Applicable
Method of Concealment	Not Applicable
Blinding/Masking	Not Applicable

Primary Outcome

Outcome	Timepoints
safety and efficacy end points. The safety end points would include measurement of serious adverse events i.,e mortality, occurrence of relapse (number and frequency of events). Laboratory assessments like complete hemogram, liver and kidney function tests, immunology profile : C3 , IgA IgM	day 2, one week, 3, 6 and 12 months

Secondary Outcome

Outcome	Timepoints
clinical and radiological assessments. clinical: visual function tests, progression of disability on EDSS, MSFC, Scripps neurological scale, SF36 questionnaire. Radiological assessment : the number of CET lesions on T2 MRI, The number of T1 hypo intense lesions from baseline to follow up	day2, one week, 3,6 and 12 months

Target Sample Size	**Total Sample Size=**15 **Sample Size from India=**15
Phase of Trial	Phase 1/ Phase 2
Date of First Enrollment (India)	23/12/2014
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**3 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	none
Brief Summary	Multiple Sclerosis is an immune mediated demyelinating disease with prevalence rate of 1.33 /100,000 of population reported in mid 80s. This work is an initiative to study safety, feasibility and efficacy of intravenous bone marrow derived mesenchymal stem cells in patients with Multiple Sclerosis. Safety end points will be based on monitoring of adverse events and efficacy end points will be be based on clinical (EDSS, MSFC, Sripps rating scale, SF-QOL), visual and radiological assessments)