

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of autologous adipose-derived mesenchymal stem cells transplantation in the treatment of multiple sclerosis in Secondary Progressive phase

Protocol summary

Study aim

Main purpose was safety of high dose adipose-tissue MSCs in Secondary Progressive MS female patients
Secondary purpose was efficacy of AT-MSC on neurophysiological functions, clinical evaluations and regulatory lymphocytes of patients

Design

we aim to design an open label phase 1/2 clinical trial to assess safety and efficacy of adipose-derived mesenchymal stem cells on 10 female with secondary progressive phase of multiple sclerosis (SPMS).

Settings and conduct

10 female with secondary progressive phase of multiple sclerosis (SPMS) were selected from MS association center and referred to Ghaem Hospital of Mashhad. Abdominal fat of patients was removed. After harvesting their adipose tissue mesenchymal stem cells (AT-MSCs) were expanded to reach to a range of 5×10^6 MSC/Kg. Then their expanded AT-MSCs were infused in 2 dosage during 2 injection space 7 days apart. Next we evaluate the effect of AT-MSCs on patients by assessment of MRI scans on baseline, 6 and 9 months after transplantation, EDSS and TCD4+CD25+FOXP3+CD127- population derived from peripheral blood on baseline, 2 weeks, 1, 3, 6 and 9 months after first injection. All assessments are done in Ghaem Hospital of Mashhad.

Participants/Inclusion and exclusion criteria

inclusion criteria are female with secondary progressive phase of multiple sclerosis (SPMS) aged under 50 years, Expanded Disability Status Scale (EDSS) score 3 -6.5, Failure to response to the available disease modifying treatments exclusion criteria are Having relapses or using steroid drugs within the month prior to trial, History of malignancy, Acute or chronic infection, Immunodeficiency, Pregnancy, Lactating woman, Cardiac, renal or hepatic failure, Positive serology for HIV, Hepatitis B, Hepatitis C, Incapability for a biopsy of

at least 50 grams of fat tissue, Treatment with any disease modifying treatment during the trial, unable to give written informed consent

Intervention groups

The effect of adipose tissue mesenchymal stem cells (AT-MSCs) on a group consist of 10 female with secondary progressive multiple sclerosis (SPMS)

Main outcome variables

Efficacy of adipose tissue mesenchymal stem cells (AT-MSCs) on neurophysiological functions identified in MRI scans, Improvement in clinical evaluations according to standard criteria and Improvement of immunological procedures by decreasing regulatory lymphocytes population.

General information

Reason for update

Acronym

ندارد

IRCT registration information

IRCT registration number: **IRCT20091127002778N1**

Registration date: **2018-01-10, 1396/10/20**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-10, 1396/10/20**

Update count: **0**

Registration date

2018-01-10, 1396/10/20

Registrant information

Name

Mahmoud Mahmoudi

Name of organization / entity

Immunology Research Center, Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3711 2611

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences, Mashhad, Iran

Expected recruitment start date

2016-08-15, 1395/05/25

Expected recruitment end date

2018-02-27, 1396/12/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of autologous adipose-derived mesenchymal stem cells transplantation in the treatment of multiple sclerosis in Secondary Progressive phase

Public title

The effect of fat-derived stem cells in treatment of multiple sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with MS according to McDonald criteria
Secondary Progressive MS according to neurologist comment and standard criteria Expanded Disability Status Scale (EDDS) score 3 -6.5 Failure to response to the available disease modifying treatments age under 50 years female

Exclusion criteria:

Having relapses within the month prior to trial Using steroid drugs within the month prior to trial History of malignancy Acute or chronic infection Immunodeficiency Pregnancy Lactating woman Cardiac, renal or hepatic failure Positive serology for HIV, Hepatitis B, Hepatitis C Incapability for a biopsy of at least 50 grams of fat tissue Treatment with any disease modifying treatment during the trial Patients unable to give written informed consent

Age

To 50 years old

Gender

Female

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: 10

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Ghoreishi building, daneshgah street, next to hoveizeh cinema

City

Mashhad

Province

Razavi Khorasan

Postal code

91735-951

Approval date

2015-08-20, 1394/05/29

Ethics committee reference number

ir.mums.rec.1394.633

Health conditions studied

1

Description of health condition studied

multiple sclerosis

ICD-10 code

G35-G37

ICD-10 code description

Demyelinating diseases of the central nervous system, multiple sclerosis

Primary outcomes

1

Description

Safety and side effects of high dose Adipose-Tissue MSCs transplantation in terms of pain

Timepoint

baseline, 1,3,6 and 9 months after AT-MSCs injection

Method of measurement

self-reported of patients

2

Description

Safety and side effects of high dose Adipose-Tissue MSCs

transplantation in terms of hypersensitivity

Timepoint

baseline, 1,3,6 and 9 months after AT-MSCs injection

Method of measurement

clinical observation

3

Description

Safety of stem cell transplantation in terms of infection

Timepoint

baseline, 1,3,6 and 9 months after AT-MSCs injection

Method of measurement

CBC, LP

Secondary outcomes

1

Description

Severity of clinical scores

Timepoint

baseline, 6 and 9 months after Adipose-Tissue MSCs transplantation

Method of measurement

clinical observation by neurologist

2

Description

assessment of neurological function

Timepoint

baseline, 6 and 9 months after After-Tissue MSCs transplantation

Method of measurement

Magnetic resonance imaging (MRI)

3

Description

assessment of Tregulatory CD4+CD25+FOXP3+ percentage and lack of CD127 in peripheral blood of patients

Timepoint

baseline,1,3, 6 and 9 months after AT-MSCs transplantation

Method of measurement

Flowcytometry

Intervention groups

1

Description

intervention:Adipose-Tissue Mesenchymal Stem Cells in a amount of 5×10^6 MSC/Kg, each dosage include 2.5×10^6 MSC/Kg into MS patients, 2 dosage during 2 injection space 7 days apart

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Mahmoud Mahmoudi

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BuAli Research Institute, Ferdowsi Square, BuAli Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Mashhad, Vakilabad boulevard, Bahonar Street, School of Pharmacy, Pharmaceutical Sciences

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mahmoud Mahmoudi

Position

Professor of Mashhad Immunology Department

Latest degree

Ph.D.

Other areas of specialty/work

Immunology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Mahmoud Mahmoudi

Position

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Latest degree

Ph.D.

Other areas of specialty/work

Immunology

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Forouzan Yousefi

Position

Ph.D. student of Immunology

Latest degree

Master

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data including video, self-reported documents and specific participant data sets can be share

When the data will become available and for how long

Availability start one month after publishing article

To whom data/document is available

Researchers and academic institutions

Under which criteria data/document could be used

If researchers and academic institutions need files for more research and scientific queries, are permitted to analysis in related to targeted purposes

From where data/document is obtainable

Access to principle investigator is possible by respectively: Email, Contact information, Fax, Attendance in the institute which principle investigator is engaged in. Email: MahmoudiM@mums.ac.ir Phone: +98

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phone:00985138022229 Street address: BouAli Research
Institute, Ferdowsi Square, BouAli Square

**What processes are involved for a request to access
data/document**

If we ensure that researchers and academic institutions
need files for more research and scientific queries, They
will access into files up to two weeks

Comments