

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 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  $5 \times 10^6$  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**

mahmoudim@mums.ac.ir

**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<sup>6</sup> MSC/Kg, each dosage include 2.5×10<sup>6</sup> 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

**Street address**

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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tafaghodim@mums.ac.ir

**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**

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 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**

Immunology

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Forouzan.mania@gmail.com

**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

51 7112 6111 Mobile: +98 915 115 6304 Work  
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**