

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Autologous mesenchymal stem cell transplantation in the treatment of type 1 diabetic patients

Protocol summary

Summary

In this study we aim to examine the effect of mesenchymal stem cell transplantation on treatment of type 1 diabetic patients. Clinical trial is performed on 20 type 1 diabetic patients aged 5 to 30 years who are in stages before the onset of severe irreversible complications ,have FBS level less than 200 mg/dl and have diabetes for up to 20 weeks. Patients who have history of DKA presentations or have acute infectious diseases are excluded from the trial. Adult human MSCs are isolated from the healthy bone marrow of patients and cultured. Patients receive 2 injections with the interval of 3 months and dose of 2 million MSCs/kg. Before and 3, 6, 12 months after the first injection the clinical and paraclinical indexes of patients are assessed

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138810271414N8**

Registration date: **2010-04-06, 1389/01/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-04-06, 1389/01/17

Registrant information

Name

Bagher Larijani

Name of organization / entity

Endocrinology & Metabolism Research Center, Tehran
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8822 0037

Email address

emrc@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Endocrinology & Metabolism Research Center, Dr.Shariati
hospital

Expected recruitment start date

2010-01-15, 1388/10/25

Expected recruitment end date

2010-03-16, 1388/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Autologous mesenchymal stem cell transplantation in the
treatment of type 1 diabetic patients

Public title

Mesenchymal stem cell transplantation in the treatment
of type 1 diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: signing informed consent, presence of
type 1 diabetes, age 5-30 years, duration of diabetes up
to 20 weeks, being in stages before the onset of severe
irreversible complications Exclusion criteria: history of
DKA presentation, having acute infectious diseases

Age

From **5 years** old to **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked
No information

Sample size
Target sample size: 20

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
Endocrinology & Metabolism Research Center,
Dr.Shariat hospitali

Street address
5th floor, Dr.Shariati hospital, North Kargar avenue,
Tehran, Iran

City
Tehran

Postal code

Approval date
empty

Ethics committee reference number
E-0069

Health conditions studied

1

Description of health condition studied
Type 1 diabetes

ICD-10 code
E10

ICD-10 code description
Insulin-dependent diabetes mellitus

Primary outcomes

1

Description
CD markers

Timepoint
3 months

Method of measurement
serum analysis

2

Description
anti insulin Ab

Timepoint
3 months

Method of measurement
serum analysis

3

Description
anti receptor Ab

Timepoint
3 months

Method of measurement
serum analysis

4

Description
anti GAD

Timepoint
3 months

Method of measurement
serum analysis

5

Description
c-peptide

Timepoint
3 months

Method of measurement
serum analysis

6

Description
HbA1c

Timepoint
3 months

Method of measurement
blood sample analysis

7

Description
insulin dose

Timepoint
3 months

Method of measurement
mean dose of insulin injected in one week

8

Description
mean of FBS

Timepoint
3 months

Method of measurement
blood sample

9

Description

mean of BS

Timepoint

3 months

Method of measurement

blood sample

Secondary outcomes

empty

Intervention groups

1

Description

autologous mesenchymal stem cell transplantation

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrinology & Metabolism Research Center,
Dr.Shariati hospital

Full name of responsible person

Dr. Nasli - Dr.Mojahed - Dr. Amini

Street address

5th floor, Dr.Shariati hospital, North Kargar avenue,
Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Endocrinology & Metabolism Research Center

Full name of responsible person

Dr. Larijani

Street address

5th floor, Dr.Shariati hospital, North Kargar avenue,
Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Endocrinology & Metabolism Research Center

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact

Name of organization / entity

Endocrinology & Metabolism Research Center,
Dr.Shariati Hospital

Full name of responsible person

Dr. Larijani

Position

Professor

Other areas of specialty/work

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5th floor, Dr.Shariati hospital, North Kargar avenue,
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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Endocrinology & Metabolism Research Center,
Dr.Shariati Hospital

Full name of responsible person

Dr. Nasli

Position

Assistant professor

Other areas of specialty/work

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Email

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty