

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Transplantation of allogenic mesenchymal stem cells (MSCs) derived from placenta and adipose tissue for the treatment of type 1 diabetes mellitus (T1DM): a clinical trial, phase 1 and 2.

Protocol summary

Study aim

To evaluate the safety and therapeutic effects of allogeneic MSCs transplantation (placenta and adipose tissue derived) in the treatment of T1DM.

Design

A double-blind randomized clinical trial with a parallel group design on 30 patients (10 patients in each group).

Settings and conduct

In this double-blind randomized clinical trial, 30 volunteer T1DM patients aged ≥ 18 from both sexes which diagnosed within 1 year will be recruited and randomly divided into three groups of control, Intervention group-1 and Intervention group-2 by sealed envelope software. After injection of MSCs, all grouped are followed for 1 year.

Participants/Inclusion and exclusion criteria

Inclusion criteria: - All adults (≥ 18 year) with T1DM which diagnosis less than 1 year from the onset of diabetes - Have at least one T1DM related autoantibody
Exclusion criteria: - Inability to fill informed consent - Pregnancy in women - Having any chronic complication of diabetes including nephropathy, retinopathy and vascular complications - Having a serious infection or have a positive test for hepatitis B, hepatitis C or HIV - Having other chronic comorbidities such as psychological, cardiovascular, renal, pulmonary, liver, hematologic and other serious autoimmune diseases (except T1DM or Hashimoto's disease) - History of cancer - History of diabetic ketoacidosis

Intervention groups

Intervention group-1: In this group, patients will be given allogeneic adipose tissue derived MSCs (single IV infusion of 1×10^6 cells/kg suspended in 100 mL of normal saline). Intervention group-2: In this group, patients will be given allogeneic placenta tissue derived MSCs (single IV infusion of 1×10^6 cells/kg suspended in 100 mL of normal saline). Control group: 100 mL of

normal saline (single IV infusion).

Main outcome variables

Daily insulin requirement; HbA1c; Basal and stimulated C-peptide level; Side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210925052566N1**

Registration date: **2022-01-23, 1400/11/03**

Registration timing: **prospective**

Last update: **2022-01-23, 1400/11/03**

Update count: **0**

Registration date

2022-01-23, 1400/11/03

Registrant information

Name

Sayed Mahmoud Sajjadi Jazi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8822 0038

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2023-05-22, 1402/03/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Transplantation of allogenic mesenchymal stem cells (MSCs) derived from placenta and adipose tissue for the treatment of type 1 diabetes mellitus (T1DM): a clinical trial, phase 1 and 2.

Public title
Transplantation of stem cells for the treatment of type 1 diabetes.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 All adults (≥ 18 year) with T1DM which diagnosis less than 1 year from the onset of diabetes Have at least one T1DM related autoantibody
Exclusion criteria:
 Inability to fill informed consent Pregnancy in women Having any chronic complication of diabetes including nephropathy, retinopathy and vascular complications Having a serious infection or have a positive test for hepatitis B, hepatitis C or HIV Having other chronic comorbidities such as psychological, cardiovascular, renal, pulmonary, liver, hematologic and other serious autoimmune diseases (except T1DM or Hashimoto's disease) History of cancer History of diabetic ketoacidosis

Age
From **18 years** old

Gender
Both

Phase
1-2

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization method with block sizes of 3 will be use to randomize individuals using sealedenvelope online software (<https://www.sealedenvelope.com/simple-randomiser/v1/ists>). Allocation concealment will be carry out.

Blinding (investigator's opinion)
Double blinded

Blinding description
After randomization by sealedenvelope online software, the codes which generated by software are placed on stem cell or placebo bags by the stem cell production laboratory (stem cell and placebo bags are similar), both participants and researchers do not know the codes and are unaware of the study groups. The codes will be

decrypted only after the end of the study or when serious complications occur.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Central Building of Tehran University of Medical Sciences, Qods St., Keshavarz Blvd.

City

Tehran

Province

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Postal code

1417653761

Approval date

2021-09-15, 1400/06/24

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.669

Health conditions studied

1

Description of health condition studied

Type 1 diabetes mellitus (T1DM)

ICD-10 code

E10

ICD-10 code description

Type 1 diabetes mellitus

Primary outcomes

1

Description

Daily insulin requirement

Timepoint

Before intervention and 1, 2, 3, 4, 8, 12, 24, 36, 48 weeks after intervention

Method of measurement

Total daily Insulin Requirement (in units of insulin)

2

Description

HbA1c

Timepoint

Before intervention and 1, 3, 6, 9, 12 month after intervention

Method of measurement
Blood sample

3

Description
Basal and stimulated C-peptide level

Timepoint
Before intervention and 1, 3, 6, 9, 12 month after intervention

Method of measurement
Blood sample

Secondary outcomes

1

Description
Side effects

Timepoint
Before intervention and 1, 2, 3, 4, 8, 12, 24, 36, 48 weeks after intervention

Method of measurement
History and physical examination

Intervention groups

1

Description
Intervention group-1: In this group, patients will be given allogeneic adipose tissue derived MSCs (single intravenous [IV] infusion of 1×10^6 cells/kg suspended in 100 mL of normal saline).

Category
Treatment - Drugs

2

Description
Intervention group-2: In this group, patients will be given allogeneic placenta tissue derived MSCs (single IV infusion of 1×10^6 cells/kg suspended in 100 mL of normal saline).

Category
Treatment - Drugs

3

Description
Control group: 100 mL of normal saline (single IV infusion).

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Dr. Shariati Hospital

Full name of responsible person
Sayed Mahmoud Sajjadi Jazi

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2

Recruitment center

Name of recruitment center
Clinic of Diabetes and Metabolic Diseases

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Endocrinology and Metabolism Research Institute

Full name of responsible person
Dr. Bagher Larijani

Street address
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http://emri.tums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Endocrinology and Metabolism Research Institute
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
Tehran University of Medical Sciences
Full name of responsible person
Sayed Mahmoud Sajjadi Jazi
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All collected deidentified IPD

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

Only available for people working in academic institutions

Under which criteria data/document could be used

The data can be analyzed after obtaining permission from the principal investigator

From where data/document is obtainable

Email to principal investigator m_sajadi@tums.ac.ir

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

Email to primary investigator

Comments