

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

phase I clinical trial placental mesenchymal stem cell therapy for the treatment of type 1 diabetes mellitus

Protocol summary

Study aim

main goal is to access the safety of treatment with placental mesenchymal stem cell in new onset T1DM patients.

Design

10 eligible new onset T1DM patients with 12-18 yr age will be enrolled in this phase one clinical trial. no blinding and single group clinical trial will be done and placental mesenchymal stem cell will be transplanted with clinical grade standard .

Settings and conduct

new onset T1DM patients with less than 6 month from Diagnosis will be enrolled. intravenous injection of clinical grade placental mesenchymal stem cell-which cultured in endocrinology and metabolism research institute- will be done after taken inform consent from patients in children medical center . before and after placental mesenchymal stem cell transplantation we will check laboratory parameter of diabetes mellitus, insulin consumption, and adverse events and visit the patients in intervals before and after transplantation for 1 year.

Participants/Inclusion and exclusion criteria

inclusion criteria both gender 12-18 years old type one diabetes mellitus at least one positive auto antibody of T1DM in first 6 month of diagnosis Exclusion criteria malignancy simultaneous auto immune disorders pregnancy DKA presentation chronic disorder

Intervention groups

transplantation of placental mesenchymal stem cell from peripheral vein and with dose 2 million per new onset diabetic patient kilogram weight

Main outcome variables

HbA1c level; c-peptide level; T1DM auto antibodies; FBS and PPG; insulin requirement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171021036903N2**

Registration date: **2019-12-24, 1398/10/03**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-24, 1398/10/03**

Update count: **0**

Registration date

2019-12-24, 1398/10/03

Registrant information

Name

sedigheh madani

Name of organization / entity

EMRI

Country

Iran (Islamic Republic of)

Phone

+98 21 8863 1298

Email address

s_madani@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2021-03-21, 1400/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

phase I clinical trial placental mesenchymal stem cell therapy for the treatment of type 1 diabetes mellitus

Public title

The safety of placental mesenchymal stem cell therapy for the treatment of type 1 diabetes mellitus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

both gender 12-18 years old type one diabetes mellitus at least one positive auto antibody of T1DM in first 6 month of diagnosis

Exclusion criteria:

malignancy simultaneous auto immune disorders pregnancy chronic disorder other than diabetes

Age

From **12 years** old to **18 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

Not randomized

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

ethic committee of tehran university of medical science

Street address

Bolvar keshavarz street, Tehran university of medical science

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2018-01-28, 1396/11/08

Ethics committee reference number

IR.TUMS.VCR.REC.1396.4367

Health conditions studied

1

Description of health condition studied

Diabetes Mellitus type 1

ICD-10 code

E10.9

ICD-10 code description

Type 1 diabetes mellitus without complications

Primary outcomes

1

Description

daily insulin requirement

Timepoint

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

Method of measurement

daily insulin requirement per kilogram weight

2

Description

HbA1c

Timepoint

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

Method of measurement

blood sample

3

Description

c peptide level

Timepoint

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

Method of measurement

blood sample

Secondary outcomes

1

Description

life threatening major side effect

Timepoint

before and 1,3,6 ,12 months after intervention

Method of measurement

physical examination

Intervention groups

1

Description

one time placental mesenchymal stem cell transplantation -which produced in endocrinology and metabolism research institute of Tehran university of medical science- from peripheral vein to T1Dm patients with 2 million per kilogram weight dose

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

TUMS hospitals-Endocrinology and metabolism research institute

Full name of responsible person

Seyyedeh Sedigheh Madani

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Web page address<http://emri.tums.ac.ir/pages/mainPage.asp?l=S1M5P2C1>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

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Email

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Web page address<http://emri.tums.ac.ir/pages/mainPage.asp?l=S1M5P2C1>**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

from clinical scientist budget

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

Seyyedeh Sedigheh Madani

Position

Pediatric Endocrinology Subspecialist, Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

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Person responsible for updating data

Contact

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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

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

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

donor and recipient demographic data and recipient follow up data

When the data will become available and for how long

from beginning to the end of the study

To whom data/document is available

principal manager /the supervisor professor /ethic committee

Under which criteria data/document could be used

for analysis of the results and searching the reason of the probable side effects

From where data/document is obtainable

PI

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

PI acceptance ----- ethic committee acceptance -----
recording of this acceptance and the amount of data that should be given and the result that should be achieved

Comments