Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 requirment

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

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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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emrc@tums.ac.ir
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http://emri.tums.ac.ir/pages/mainPage.asp?I=S1M5P2C1

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Bagher Larijani
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Email
emrc@tums.ac.ir
Web page address
http://emri.tums.ac.ir/pages/mainPage.asp?I=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 updating data

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pediatric endocrinology subspecialist student

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Specialist

Other areas of specialty/work
Pediatrics

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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 fallow 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