Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Phase I Clinical Trial to Examine the Safety of Transplantation of Mesenchymal Stem Cells in New-onset Type 1 Diabetes Patients

Protocol summary

Summary

In this study, according to immunomodulatory role of mesenchymal stem cells and their role in increasing of regeneration, these cells are used to treat type-1 diabetes. Patients of both sexes in a range of 8 to 40 years old who have been diagnosed to have type-1 diabetes in no more than 6 weeks, antibody against beta cells diagnosed in their blood, fasting c-peptide more than or equal to 0.3 ng/ml, and are not suffered from other acute or chronic diseases and cancers, would be studied. In a double blinded randomized placebo-controlled phase I clinical trial, 20 patients with newly diagnosed type-1 diabetes who visited in Children's Growth and Development Research Center of Tehran University of Medical Sciences and Royan Institute Cell Therapy Center, would be assessed through two groups including the case group (1 million autologous mesenchymal stem cells per kg of patient's body weight in each dose, week 0 and 3) and the placebo group. Interventions: Intravascular transplantation of 1 million autologous mesenchymal stem cells per kg of patient's body weight in each dose in week 0 and 3 in the case group & placebo injection in the control group. Outcome variables: safety of this treatment in weeks 1, 2, 3, Months 1, 2, 3, 6, 9 & 12 after first injection will be evaluated.

General information

Acronym

MSCTX-T1DM

IRCT registration information

IRCT registration number: **IRCT2016070428786N1**
Registration date: **2016-08-20, 1395/05/30**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-08-20, 1395/05/30

Registrant information

Name

Hossein Baharvand

Name of organization / entity

Royan Institute

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Royan Institute

Expected recruitment start date

2015-12-23, 1394/10/02

Expected recruitment end date

2017-08-24, 1396/06/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Phase I Clinical Trial to Examine the Safety of Transplantation of Mesenchymal Stem Cells in New-onset Type 1 Diabetes Patients

Public title

Mesenchymal Stem Cells Transplantation in newly diagnosed Type-1 Diabetes Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Type 1 diabetes detection in less than 6 weeks; diabetes diagnosis according to American Diabetes Association; Presence of Antibodies against pancreatic beta cells; Both Sexes; Age: 8-40 years; Fasting C-peptide ≥ 0.3 ng/ml Exclusion Criteria: Pregnancy or breastfeeding; Cancer; Any acute or severe disease (According to physicians diagnosis: such as cardiac, pulmonary, hepatic, kidney, mental,... diseases); Positive results for: HIV, HTLV, HBV, HCV, CMV; Immune deficient or hyper aesthesia; History of ketoacidosis

Age
From **8 years** old to **40 years** old

Gender
Both

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Royan Institute

Street address
Hafez st.- Northern Banihashem Ave.- Resalat Exp. Way

City
Tehran

Postal code
19395-4644

Approval date
2015-12-08, 1394/09/17

Ethics committee reference number
IR.ACECR.ROYAN.REC.1394.50

Health conditions studied

1

Description of health condition studied
Diabetes

ICD-10 code
E10

ICD-10 code description
Insulin-dependent diabetes mellitus

Primary outcomes

1

Description
Safety

Timepoint
weeks 1,2,3, Months 1,2,3,6,9 & 12

Method of measurement
Assessment based on evaluater & subjects

Secondary outcomes

1

Description
Hypoglycemic Unawareness episodes

Timepoint
weeks 1,2,3, Months 1,2,3,6,9 & 12

Method of measurement
Assessment based on evaluater & subjects

2

Description
fasting C-peptide enhancement

Timepoint
weeks 1,2,3, Months 1,2,3,6,9 & 12

Method of measurement
Blood Test

3

Description
Patient's Metabolic indexes enhancement

Timepoint
weeks 1,2,3, Months 1,2,3,6,9 & 12

Method of measurement
Assessing HbA1C, C-peptide & Insulin demand of patients

Intervention groups

1

Description
Case group: Intravenous injection of 1 million autologous mesenchymal stem cells per kg of patient’s body weight in each dose, week 0 and 3

Category
Treatment - Other

2

Description
Control: Receive placebo

Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Royan Institute
Full name of responsible person
Ensiyeh Hajizadeh Saffar
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2

Recruitment center
Name of recruitment center
Children's Growth and Development Research Center
Full name of responsible person
Ali Rabani
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Children's Medical Center- Dr Gharib St.
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Royan Institute
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
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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