

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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)

Phone

+98 21 2230 6485

Email address

baharvand@royaninstitute.org

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 $\geq$ 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 evaluator & 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 evaluator & 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

Street address

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

City

Tehran

2

Recruitment center

Name of recruitment center

Children's Growth and Development Research Center

Full name of responsible person

Ali Rabani

Street address

Children's Medical Center- Dr Gharib St.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Royan Institute

Full name of responsible person

Hamid Gourabi

Street address

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

City

Tehran

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

Name of organization / entity

Royan Institute

Full name of responsible person

Ensiyeh Hajizadeh Saffar

Position

MD\PhD in Medical Biotechnology

Other areas of specialty/work

Street address

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

City

Tehran

Postal code

16635-148

Phone

+98 21 2233 9949

Fax

Email

hajizadeh.ehs@gmail.com

Web page address

www.royaninstitute.org

Person responsible for scientific inquiries

Contact

Name of organization / entity

Royan Institute

Full name of responsible person

Hossein Baharvand

Position

PhD in Developmental Biology

Other areas of specialty/work

Street address

Royan Institute for Stem cells Biology and
Technology- Royan Institute- Hafez St.- Northern
Banihashem Ave.- Resalat Exp Way

City

Tehran

Postal code

16635-148

Phone

+98 21 2230 6485

Fax

+98 21 2356 2507

Email

baharvand@royaninstitute.org

Web page address

www.royaninstitute.org

Person responsible for updating data

Contact

Name of organization / entity

Royan Institute

Full name of responsible person

Mahmoud Izadi

Position

MSc in Medical Biotechnology

Other areas of specialty/work**Street address**

3rd floor- Royan Institute Cell Therapy Center- No. 9-
Shaghayegh Dead end- Northern Banihashem
Avenue- Resalat Exp. Way

City

Tehran

Postal code

16635-148

Phone

+98 21 2231 0368

Fax

+98 21 8879 3329

Email

ma14i@yahoo.com

Web page address

www.royaninstitute.org

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