Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigation on autologous mesenchymal stem cell transplantation in diabetic retinopathy

Protocol summary

Summary

In the beginning, among patients with type one diabetes who been diagnosed diabetic retinopathy and volunteers for cell therapy, twenty patients will be selected. All stages of the project explain for each patients, then if they want to enter the project inform consent would be obtained from each patients. Then, from all participants asked to take SMBG for at least one month. after that each patients take laboratory samples for FBS and HbA1C at laboratory of EMRI. Then, mesenchymal stem cells obtained via bone marrow aspiration would be cultured. Each patients receive 2 millionmesenchymal stem cell per kilogram by IV injection. Optic Coherence Tomography(OCT), retinal artery flow (by Angiography fluorescein) and visual acuity according to the chart Snellen will be examined in our patient at regular interval : One week before, a month later, two months, six and nine months after cell treatment and visited by medical team ,and according to the protocol follow up test will be done. Expecting by both development of these cells into retinal cells and regulation of immune system (which has an important role in the improvement of diabetes) lead to improve function of eyes in patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111291414N29**
Registration date: **2012-08-14, 1391/05/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-08-14, 1391/05/24

Registrant information

Name

Bagher Larijani

Name of organization / entity

Endocrinology & Metabolism Research Center, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8822 0037

Email address

emrc@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Endocrinology and Metabolism Research Institute of Tehran University of Medical Sciences

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2013-06-22, 1392/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation on autologous mesenchymal stem cell transplantation in diabetic retinopathy

Public title

Investigation on autologous mesenchymal stem cell transplantation in diabetic retinopathy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:People with diabetes type one with at least 10 years duration ;Age 18-40 years;Signing informed consent;Patients with diabetic retinopathy

diagnosed by an ophthalmologist ;HbA1c ≤ 7.5% (blood glucose is controlled at least for one month);All eligible patients for celltherapy (according to standard protocol); BP≤130/80 ;Cardiac Consultation form that is filled by a cardiologist (Cardiac echocardiography and ECG)
Exclusion criteria: Acute vascular inflammation ; Acute thrombosis (three months); Pulmonary hypertension;Liver disease; Hematological malignancy and bone marrow cancer;Infectious diseases;Mental illness; Generalized edema ; Malignancy; pregnancy ; Sensitivity to the fluorescein

Age
From **18 years** old to **40 years** old

Gender
Both

Phase
0

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features
This is an interventional study to evaluate the effect autologous transplant of bone marrow stem cells for patients with diabetes type one.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Endocrine & Metabolism Research Institute Tehran University Of Medical Sciences

Street address
ShariatiHospital,North KargarSt

City
Tehran

Postal code
1411413137

Approval date
2011-12-28, 1390/10/07

Ethics committee reference number
E-00182

Health conditions studied

1

Description of health condition studied
diabetic retinopathy (dibetes type one)

ICD-10 code
H36.0*

ICD-10 code description
Diabetic retinopathy

Primary outcomes

1

Description
Retin blood Flow

Timepoint
Optic Coherence Tomography(OCT), retinal artery flow (by Angiography fluorescence) and visual acuity according to the chart Snellen will be examined in our patient at regular interval : One week before, a month later, two months, six and nine months after cell treatment and visited by medical team ,and according to the protocol follow up test will be done.

Method of measurement
Fluorescein Angiography

Secondary outcomes

1

Description
Optic Coherence

Timepoint
One week before, one, two, six and nine months after intervention

Method of measurement
Optic Coherence Tomgtaphy

Intervention groups

1

Description
Once Injection 2 million cells per kilogram of body weight of autologous mesenchymal stem cells were taken from the bone marrow amount of 50 ml during 30 minutes for one time.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Endocrinology & Metabolism Research Institute

Full name of responsible person
Dr. Nasli- Dr.Razmandeh

Street address
5th floor, Dr.Shariati hospital, North Kargar avenue

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The EMRI Endocrinology and Metabolism Research Institute ، Tehran University of Medical Sciences

Full name of responsible person

Dr.Ramin Heshmat

Street address

5th floor, Dr.Shariati hospital, North Kargar avenue

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

The EMRI Endocrinology and Metabolism Research Institute ، Tehran University of Medical Sciences

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Professor

Full name of responsible person

Dr. Larijani

Position

Endocrinology & Metabolism Research Center, Dr.Shariati Hospital

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

The EMRI Endocrinology and Metabolism Research Institute , Tehran University of Medical Sciences

Full name of responsible person

Dr. Nasli ,Dr.Razmandeh

Position

Assistant professor, General Practitioner

Other areas of specialty/work

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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