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 million mesenchymal 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
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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 cell therapy (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
Shariati Hospital, North Kargar St

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 (diabetes 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 Tomography

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

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

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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**  
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**  
empty

**Type of organization providing the funding**  
empty

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**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**  
The EMRI Endocrinology and Metabolism Research Institute, Tehran University of Medical Sciences

**Full name of responsible person**  
Dr. Larijani

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Endocrinology & Metabolism Research Center, Dr. Shariati Hospital

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**Person responsible for scientific inquiries**

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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