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
Country
Iran (Islamic Republic of)

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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
<table>
<thead>
<tr>
<th>Grant name</th>
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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. Nasli, Dr. Razmandeh

**Position**

Assistant professor, General Practitioner

**Other areas of specialty/work**

Endocrinology & Metabolism Research Center, Dr. Shariati Hospital

**Street address**

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**Phone**

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r.razmandeh1388@gmail.com

**Web page address**

http://emri.tums.ac.ir

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### 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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**City**

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**Postal code**

1411413137

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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