

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Aug 2026

### Investigation on autologous mesenchymal stem cell transplantation in diabetic nephropathy (type one)

#### Protocol summary

##### Summary

1-Objectives, Investigation on autologous mesenchymal stem cell transplantation in diabetic nephropathy (type one) 2-Design, In the beginning, among patients with type one diabetes nephropathy who eligible for inclusion criteria and volunteer for cell therapy, twenty patients will be selected. 3-Setting and conduct, 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 Diabetes and Metabolic Diseases Clinic. Then, mesenchymal stem cells (MSCs) obtained via bone marrow aspiration would be cultured. After preparation of the cells, each patients receive MSCs by IV injection. One week before, a month later, three months, six, 12 and 24 months after cell treatment the patient will be examined and visited by medical team, and according to the protocol follow up test will be done. 4- Participants including major eligibility criteria, Type 1 diabetic nephropathy with  $30 \leq \text{GFR} \leq 45(\text{mL/min/1.73 m}^2)$  5- Intervention, Each patients receive 2 million MSCs / kg by IV injection. 6- main outcome measures (variables), Include Glomerular Filtration Rate (GFR) and Albumin/Creatinine ratio.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201111291414N28**

Registration date: **2012-07-29, 1391/05/08**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-07-29, 1391/05/08

##### 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 (EMRI)

##### Expected recruitment start date

2012-07-22, 1391/05/01

##### Expected recruitment end date

2013-07-23, 1392/05/01

##### 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 nephropathy (type one)

##### Public title

Investigation on autologous mesenchymal stem cell transplantation in diabetic nephropathy (type one)

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: 1. signing informed consent 2. People

with diabetes type one with at least 10 years duration 3. age 18-40 years 4. Diabetic nephropathy diagnosed by nephrologists 5. HbA1c  $\leq$  7.5% (blood glucose is controlled at least for one month) Exclusion criteria: 1. acute vascular inflammation 2. acute thrombosis (three months) 3. recent bleeding in the retina (the last three months) 4. pulmonary hypertension 5. liver disease 6. tumors in bone marrow or any malignancy is diagnosed 7. infectious diseases 8. mental illness 9. generalized edema 10. malignancy 11. pregnancy 12. Diastolic blood pressure  $\geq$ 110 13. Cigar Smoker

**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****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics commttee of Tehran Medical University of Science

**Street address**

ShariatiHospital,North KargarSt,1411413137

**City**

Tehran

**Postal code****Approval date**

2010-08-20, 1389/05/29

**Ethics committee reference number**

E-00182

**Health conditions studied****1****Description of health condition studied**

Diabetes Nephropathy (type 1)

**ICD-10 code**

N08.3

**ICD-10 code description**

Glomerular disorders in diabetes mellitus

**Primary outcomes****1****Description**

GFR

**Timepoint**

Before intervention(time 0) and 4,12,24,48,96 weeks after cell infusion

**Method of measurement**

using MDRD and Cockcroft-Gault formula-ml/min/1.73square meter

**2****Description**

Albumin/Creatinine ratio

**Timepoint**

Before intervention(time 0) and 4,12,24,48,96 weeks after cell infusion

**Method of measurement**

mg/mmol

**Secondary outcomes****1****Description**

C-peptide

**Timepoint**

Before intervention(time 0) and 4,12,24,48,96 weeks after cell infusion

**Method of measurement**

ng/ml

**2****Description**

Cr

**Timepoint**

Before intervention(time 0) and 4,12,24,48,96 weeks after cell infusion

**Method of measurement**

mg/dl

**3****Description**

BUN

**Timepoint**

Before intervention(time 0) and 4,12,24,48,96 weeks after cell infusion

**Method of measurement**

mg/dl

#### 4

**Description**

HbA1c

**Timepoint**

Before intervention(time 0) and 4,12,24,48,96 weeks after cell infusion

**Method of measurement**

%

#### 5

**Description**

FBS

**Timepoint**

Before intervention(time 0) and 4,12,24,48,96 weeks after cell infusion

**Method of measurement**

mg/dl

### Intervention groups

#### 1

**Description**

Injection of autologous mesenchymal stem cell

**Category**

Treatment - Other

### Recruitment centers

#### 1

**Recruitment center****Name of recruitment center**

Diabetes and metabolic diseases clinic

**Full name of responsible person**

Dr Nasli

**Street address**

Next to south entrance door of Tehran Heart Center,North KargarSt

**City**

Tehran

### Sponsors / Funding sources

#### 1

**Sponsor****Name of organization / entity**

Endocrinology and Metabolism Research Institute (EMRI)

**Full name of responsible person**

Dr Ramin Heshmat

**Street address**

Shariati Hospital, North KargarSt, Endocrinology and Metabolism Research Institute (EMRI)

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor****organization/entity?**

Yes

**Title of funding source**

Endocrinology and Metabolism Research Institute (EMRI)

**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**

Endocrinology and Metabolism Research Institute (EMRI)

**Full name of responsible person**

Dr Bagher Larijani

**Position**

Professor

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

Shariati Hospital, North KargarSt, Endocrinology and Metabolism Research Institute (EMRI)

**City**

Tehran

**Postal code**

1411413137

**Phone**

+98 21 8822 0037

**Fax**

+98 21 8822 0052

**Email**

emrc@tums.ac.ir

**Web page address**

http://emri.tums.ac.ir

### Person responsible for updating data

**Contact****Name of organization / entity**

Endocrinology and Metabolism Research Institute (EMRI)

**Full name of responsible person**

Maryam Ghodsi

**Position**

MD

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

Shariati Hospital, North KargarSt, Endocrinology and Metabolism Research Institute (EMRI)

**City**  
Tehran  
**Postal code**  
1411413137  
**Phone**  
+98 21 8833 4192  
**Fax**  
+98 21 8800 3700  
**Email**  
emrc@tums.ac.ir  
**Web page address**  
<http://emrc.tums.ac.ir>

## 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*