

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### A phase I clinical trial on the use of autograft mesenchymal stem cells for treatment of diabetic chronic kidney disease

#### Protocol summary

##### Summary

The goal of our study is to assess the immunity and feasibility of using bone marrow stem cells for treatment of renal failure. The most important inclusion criterion is presence of stage III diabetic nephropathy (GFR between 30 to 60 ml / min /1.73 m<sup>2</sup>) and the main exclusion criterion is presence of renal artery stenosis. We select 10 patients of Labafi Nejad Hospital suffering from renal failure secondary to diabetes mellitus and after receiving their written consents, take stem cell sample. Subsequently, mesenchymal stem cells will be separated after being cultured and will be injected back into the patient's peripheral vein. Patients will be followed up regarding kidney function through laboratory tests (BUN and Creatinine) and possible complications for a period of one year.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138804091267N19**

Registration date: **2009-07-14, 1388/04/23**

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

Last update:

Update count: **0**

##### Registration date

2009-07-14, 1388/04/23

##### Registrant information

##### Name

Mojgan Borgheie

##### Name of organization / entity

Urology and Nephrology Research Center (UNRC),  
Shahid Beheshti University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2256 7222

##### Email address

research@unrc.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Urology and Nephrology Research Center ( UNRC),  
Shahid Beheshti University, M.C.( SBMU), Tehran, I.R.  
Iran

##### Expected recruitment start date

2008-09-02, 1387/06/12

##### Expected recruitment end date

2010-09-03, 1389/06/12

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A phase I clinical trial on the use of autograft  
mesenchymal stem cells for treatment of diabetic  
chronic kidney disease

##### Public title

A phase I clinical trial on the use of autograft  
mesenchymal stem cells for treatment of diabetic  
chronic kidney disease

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Presence of stage III diabetic  
nephropathy (GFR between 30 to 60 ml / min /1.73 m<sup>2</sup>),  
controlled hypertension, Blood creatinine level less than  
2 mg/dl Exclusion criteria: History or presence of  
psychological disorders, history or presence of previous  
immune deficiencies, consumption of  
immunosuppressive drugs, presence of renal artery

stenosis

#### Age

No age limit

#### Gender

Both

#### Phase

1

#### Groups that have been masked

No information

#### Sample size

Target sample size: 10

#### 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

Urology and Nephrology Research Center ( UNRC),  
Shahid Beheshti University, M.C.( SBMU), Tehran, I.

##### Street address

UNRC, No.101, Boostan 9th St., Pasdaran Ave.,  
Tehran, I.R. Iran

##### City

Tehran

##### Postal code

1666677951

#### Approval date

2008-02-05, 1386/11/16

#### Ethics committee reference number

88

### Health conditions studied

1

#### Description of health condition studied

Diabetic Nephropathy

#### ICD-10 code

N08.3

#### ICD-10 code description

Diabetic nephropathy

### Primary outcomes

1

#### Description

Kidney function

#### Timepoint

one year after injection

#### Method of measurement

Bun, Cr

### Secondary outcomes

1

#### Description

Complication

#### Timepoint

to one year

#### Method of measurement

Billirubin

### Intervention groups

1

#### Description

Injection of separated mesenchymal stem cells to the  
patient's peripheral vein

#### Category

Treatment - Other

### Recruitment centers

1

#### Recruitment center

##### Name of recruitment center

Urology and Nephrology Research Center ( UNRC),  
Shahid Beheshti University, M.C.( SBMU), Tehran, I.

##### Full name of responsible person

##### Street address

Labafi Nejad Hospital., Boostan 9th St., Pasdaran Ave.,  
Tehran, I.R. Iran

##### City

Tehran

### Sponsors / Funding sources

1

#### Sponsor

##### Name of organization / entity

Urology and Nephrology Research Center ( UNRC),  
Shahid Beheshti University, M.C.( SBMU), Tehran, I.

##### Full name of responsible person

Shabnam Golshan

##### Street address

UNRC, No.101, Boostan 9th St., Pasdaran Ave.,  
Tehran, I.R. Iran

##### City

Tehran

#### Grant name

#### Grant code / Reference number

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

**Title of funding source**  
Urology and Nephrology Research Center ( UNRC),  
Shahid Beheshti University, M.C.( SBMU), Tehran, I.

**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*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Urology and Nephrology Research Center ( UNRC),  
Shahid Beheshti University, M.C.( SBMU), Tehran, I.

**Full name of responsible person**  
DR Naser Shakhssalim

**Position**  
Assistant Professor

**Other areas of specialty/work**

**Street address**  
UNRC, No.101, Boostan 9th St., Pasdaran Ave.,  
Tehran, I.R. Iran

**City**  
Tehran

**Postal code**  
1666677951

**Phone**  
+98 21 2256 7222

**Fax**  
+98 212277954

**Email**  
research@unrc.ir

**Web page address**  
www.unrc.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Urology and Nephrology Research Center ( UNRC),  
Shahid Beheshti University, M.C.( SBMU), Tehran, I.

**Full name of responsible person**  
Dr Pedram Kharaziha

**Position**  
MSC-MD

**Other areas of specialty/work**

**Street address**

UNRC, No.101, Boostan 9th St., Pasdaran Ave.,  
Tehran, I.R. Iran

**City**  
Tehran

**Postal code**  
1666677951

**Phone**  
+98 21 2256 7222

**Fax**  
+98 212277954

**Email**  
research@unrc.ir

**Web page address**  
www.unrc.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Urology and Nephrology Research Center ( UNRC),  
Shahid Beheshti University, M.C.( SBMU), Tehran, I.

**Full name of responsible person**  
Dr Mozghan Borgheie

**Position**  
MD

**Other areas of specialty/work**

**Street address**  
UNRC, No.101, Boostan 9th St., Pasdaran Ave.,  
Tehran, I.R. Iran

**City**  
Tehran

**Postal code**  
1666677951

**Phone**  
+98 21 2256 7222

**Fax**  
+98 212277954

**Email**  
borgheie@unrc.ir

**Web page address**  
www.unrc.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*