

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 m²) 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 m²),
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