

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Sep 2026

Evaluation of effects of injected autologous mesenchymal stem cells on kidney function in patients with chronic kidney disease

Protocol summary

Summary

Objectives This project intends to assess, up to one year, the role of autologous mesenchymal stem cells in improvement of kidney function in patients with chronic kidney disease (CKD). Therefore the main and practical objective of this study is to evaluate the effect of intravenous injection of autologous mesenchymal stem cells on kidney function trends. **Design:** In this study, 15 male and female CKD patients who have a GFR between 15-30 ml/ml will be enrolled. **Setting and conduct, participants and intervention:** Patients will be selected from a list of patients attending the nephrology clinic of Dr. Shariati Hospital. After obtaining the consent form, the bone marrow aspiration will be performed by hematologist and then in the specialized lab, the mesenchymal stem cells will be separated and cultured to reach appropriate number (106/kg). The cells will be injected through peripheral vein in hospital setting. **Patients will be followed-up (clinically and laboratory) every two months up to one year.** The clinical assessment and necessary biochemical tests will be performed in each visit. The trends of kidney function (serum creatinin and GFR) in last year before injection for each patient will be regarded as the control for that patient. **Outcome measures:** Periodic assessments of serum BUN and creatinin, urine protein and creatinin, GFR and clinical evaluation of patients for high blood pressure or probable complications.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204248349N1**

Registration date: **2015-05-10, 1394/02/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-05-10, 1394/02/20

Registrant information

Name

Iraj Najafi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Presidency of the Islamic Republic of Iran, Vice-Presidency for Science and Technology

Expected recruitment start date

2014-01-30, 1392/11/10

Expected recruitment end date

2016-12-30, 1395/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effects of injected autologous mesenchymal stem cells on kidney function in patients with chronic kidney disease

Public title

Effects of mesenchymal stem cell therapy in patients with chronic kidney disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 1-CKD patient 2- GFR between 15-30 mml/min 3- No serious underlying disease 4- Availability of previous medical records for creatinin and GFR 5- Age between 18-65 years The necessary information will be given to patients before enrollment and patient will sign the consent form. Exclusion Criteria: 1- Serious mental disorders (suicide history, major depression) 2- Patients who cannot come for regular visits 3- Less than one year survival 4- Patients who use immunosuppressive drug 5- Pregnancy 6- Congestive Heart Failure (CHF) 7- Malignancy 8- Coagulation disorders 9- Uncontrolled hypertension 10- Positive virology tests 11- Infection or osteomyelitis in bone marrow aspiration site 12- Hb<8 g/dL, platelet <100,000

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **15**

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

Sciences Ethics committee of Tehran University Of Medical Sciences

Street address

6th floor, central building of TUMS, Ghods street, Keshavarz Blv, Tehran, Iran

City

Tehran

Postal code

1417653761

Approval date

2012-02-22, 1390/12/03

Ethics committee reference number

90/D/2310/130

Health conditions studied

1

Description of health condition studied

Chronic Kidney Disease (CKD)

ICD-10 code

N18.1, N18

ICD-10 code description

Kidney damage with decreased GFR

Primary outcomes

1

Description

Blood pressure

Timepoint

Before and every two months after intervention up to one year

Method of measurement

Mercury sphygmomanometer

2

Description

Serum creatinin

Timepoint

Baseline and every two months after intervention up to one year

Method of measurement

Autoanalyser

3

Description

Glomerular filtration rate (GFR)

Timepoint

Baseline and every two months after intervention up to one year

Method of measurement

MDRD formula

4

Description

Urine creatinin

Timepoint

Baseline and every two months after intervention up to one year

Method of measurement

24 h urine collection

5

Description

Urine Protein

Timepoint

Baseline and every two months after intervention up to one year

Method of measurement

24 h urine collection

Secondary outcomes

1

Description

Need to dialysis

Timepoint

Baseline and every two months after intervention

Method of measurement

Serum creatinin

2

Description

Stem cell injection complications

Timepoint

Baseline and every two months after intervention

Method of measurement

Biochemical and clinical assessment of patients

Intervention groups

1

Description

Intervention group: single peripheral injection of autologous mesenchymal stem cells (1,000,000/kg). The mesenchymal stem cells will be separated from bone marrow aspiration sample and then the cells will be cultured and proliferated in specialized lab until they reach enough numbers and then they will be injected through peripheral vein into the circulation. the injection will be performed only one time.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Shariati Hospital, Nephrology Research Center

Full name of responsible person

Dr sudabeh alatab

Street address

4th floor, Dr. Shariati Hospital, North Karger Ave,
Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Presidency of the Islamic Republic of Iran, Vice-
Presidency for Science and Technology

Full name of responsible person

Mr. Sajadian

Street address

Presidency of the Islamic Republic of Iran, Vice-
Presidency for Science and Technology, Number 7,
Avesta street, Sheikh Bahaee square, Molasadra Ave.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Presidency of the Islamic Republic of Iran, Vice-
Presidency for Science and Technology

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

Name of organization / entity

Urology research Center, Sina Hospital

Full name of responsible person

Dr. Sudabeh Alatab

Position

Medical doctor

Other areas of specialty/work

Street address

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Iraj Najafi

Position

Nephrologist

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

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Sudabeh Alatab

Position

MD

Other areas of specialty/work

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