

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

A phase I clinical trial on the use of autologous bone marrow mesenchymal stem cells for treatment of chronic kidney disease

Protocol summary

Summary

Objective: Safety and feasibility of using bone marrow-derived mesenchymal stem cells for treatment chronic renal failure. Design: Study groups: Ten CKD patients. Groups: One group, phase I. Sample size: Ten patients. Blinding: Not blinded, single center. Method: After trial description and obtaining informed consent, bone marrow aspiration will be performed and mesenchymal stem cells will be isolated and cultivated in clean room, then 1 million/kg cells in one dose will be injected into a peripheral vein of patients. Patients at first week, second week, one month and then every 3 months until 12 months after the injection will be followed up clinically and para-clinically. The trends of kidney function (serum creatinine and GFR) in last year before injection for each patient will be regarded as the control for that patient. Inclusion/exclusion criteria: Main inclusion criteria include CKD patients with glomerular filtration rate between 25-60 ml/min. Patients with diabetes, congestive heart failure, malignancy will be excluded from the trial. Intervention: One dose of peripheral vein infusion of bone marrow derived mesenchymal stem cell. The primary endpoint will be evaluated as the injection adverse event and changes in renal function, periodic assessments of serum BUN and creatinine and GFR as secondary endpoints of the study will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201509031031N17**
Registration date: **2015-12-09, 1394/09/18**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-12-09, 1394/09/18

Registrant information

Name

Nasser Aghdami

Name of organization / entity

Royan Institute

Country

Iran (Islamic Republic of)

Phone

+98 21 2356 2000

Email address

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Recruitment status

Recruitment complete

Funding source

Department of Regenerative Biomedicine, Cell Science Research Center, Royan Institute for Stem Cell Biology and Technology

Expected recruitment start date

2014-03-20, 1392/12/29

Expected recruitment end date

2016-01-20, 1394/10/30

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 autologous bone marrow mesenchymal stem cells for treatment of chronic kidney disease

Public title

Use of stem cells for treatment of chronic kidney disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: CKD confirmed with serum and urine analysis and GFR 25-60 mL/min; Male and Female; CKD (more than 3 months with increased and irreversible creatinine) symptoms; Patients with controlled hypertension; Patient's age between 40-60 years; Ability to understand and willingness to sign consent form
Exclusion Criteria: Pregnant or lactating; Vascular disease; Diabetes mellitus; Other systemic disease such as malignancy, autoimmune disease, hematologic disease, liver disease and ...; Chronic rejection in transplantation; Life expectancy less than 2 years; Allergy to any ingredients used in cell culture; Congenital or acquired obstructive chronic renal failure; Unable to attend at follow up visits

Age

From **40 years** old to **60 years** old

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

No other design features

Secondary Ids

1

Registry name

clinicaltrials.gov

Secondary trial Id

NCT02195323

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Royan infertility institute

Street address

Eastern Hafez St,Northern Banihashem St, 45 m
Resalat highway

City

Tehran

Postal code

Approval date

2014-08-12, 1393/05/21

Ethics committee reference number

EC/93/1052

Health conditions studied

1

Description of health condition studied

Chronic Kidney Disease

ICD-10 code

I12

ICD-10 code description

Hypertensive renal disease

Primary outcomes

1

Description

Mass formation

Timepoint

Every three months

Method of measurement

Sonography

2

Description

Creatinine

Timepoint

1,3,6,9,12 months after cell transplantation

Method of measurement

Blood Test

Secondary outcomes

1

Description

eGFR

Timepoint

1,3,6,9,12 months after cell transplantation

Method of measurement

Scan isotope and GFR formula

Intervention groups

1

Description

Intervention group: One dose intravenous injection of 1 million/kg bone marrow derived MSC in patients with CKD

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sari Imam Khomeini Hospital

Full name of responsible person

Atieh Makhloogh

Street address

Sari, Imam Khomeini Hospital, Beginning of Vali Asr Highway, Jouybar Three-way, Imam Square

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Department of Regenerative Biomedicine, Cell Science Research Center, Royan Institute for Stem Cell

Full name of responsible person

Hamid Gourabi

Street address

Eastern Hafez St, Northern Banihashem St, 45 m Resalat highway

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Department of Regenerative Biomedicine, Cell Science Research Center, Royan Institute for Stem Cell

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

Royan Institute

Full name of responsible person

Soroosh Shekarchian

Position

M.D/Researcher

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