Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of clinical effects of mesenchymal stem cell therapy in peritoneal dialysis patients with ultrafiltration failure, a clinical trial

Protocol summary

Summary

Objectives: This project intends to evaluate, up to 6 months, the role of autologous mesenchymal stem cells in improvement of peritoneal membrane function in peritoneal dialysis patients who have ultrafiltartion failure. Design: In this study, 10 male and female subjects who are on peritoneal dialysis for at least two years and have ultrafiltration failure with age range of 18 to 70 years will be enrolled. Setting and conduct, participants and intervention: Patients will be selected from peritoneal dialysis patients attending the peritoneal dialysis ward of Dr. Shariati hospital. The main inclusion criteria is to be on peritoneal dialysis for at least last two years and having Ultrafiltration failure. After obtaining the consent form, a small sample of fat tissue will be obtained by a general surgeon under sterilized condition frompatients and then in the specialized lab, the mesenchymal stem cells will be separated and cultured to reach appropriate numbers (106/kg). The cells will be injected through peripheral vein in hospital setting. Patients will be followed-up (clinically and laboratory) at baseline and at week 3, week 6, month 3, month 4 and month 6. The clinical assessment and peritoneal function tests will be performed in each visit. Outcome measures: The main outcome measures that periodically will be assessed include: D/P cr, D/P urea, D0/D glucose, PET, KT/V urea, Glomerular filtration rate (GFR)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015052415841N2**
Registration date: **2015-07-19, 1394/04/28**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-07-19, 1394/04/28

Registrant information

Name
Gholamreza Pourmand
Name of organization / entity
Urology Research Center,Tehran University of Medical Sciences,Tehran,Iran
Country
Iran (Islamic Republic of)
Phone
+98 21 6634 8560
Email address
pourmand@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2015-10-01, 1394/07/09

Expected recruitment end date

2016-06-01, 1395/03/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of clinical effects of mesenchymal stem cell therapy in peritoneal dialysis patients with ultrafiltration failure, a clinical trial

Public title

Effects of mesenchymal stem cells therapy in peritoneal dialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients on peritoneal dialysis; Both sexes; Age between 18-70 years; Being on peritoneal dialysis for at least last two years; Having Ultrafiltration failure Exclusion criteria: Patients who cannot come for regular visits; Patients with less than 1 year survival; Patients on immunosuppressive medications; Pregnancy; Malignancy; Coagulative disorders

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

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

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

Approval date

2015-04-29, 1394/02/09

Ethics committee reference number

IR.TUMS.REC.1394.326

Health conditions studied

1

Description of health condition studied

Chronic kidney disease

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

D/P cr

Timepoint

Before and at week 3, week 6, month 3, month 4 and month 6

Method of measurement

Ratio of 4-hour dialysate/plasma creatinine

2

Description

D/P urea

Timepoint

Before and at week 3, week 6, month 3, month 4 and month 6

Method of measurement

Ratio of 4-hour dialysate/plasma urea

3

Description

D0/D glucose

Timepoint

Before and at week 3, week 6, month 3, month 4 and month 6

Method of measurement

Ratio of dialysate glucose concentrations at end and at start of tests

4

Description

Peritoneal Equilibration Test (PET)

Timepoint

Before and at week 3, week 6, month 3, month 4 and month 6

Method of measurement

Assessment of peritoneal membrane transport function by machine

Secondary outcomes

1

Description

Glomerular filtration rate (GFR)

Timepoint

Before and at week 3, week 6, month 3, month 4 and month 6

Method of measurement

MDRD formula

2

Description
Kt/V urea
Timepoint
Before and at week 3, week 6, month 3, month 4 and month 6
Method of measurement
Dialyzer clearance of urea * dialysis time/ volume of distribution of urea

Intervention groups

1

Description
Historical control: no intervention or injection will be done in this group.
Category
Treatment - Drugs

2

Description
Intervention group: Single peripheral injection of autologous mesenchymal stem cells (1,000,000/kg). The mesenchymal stem cells will be separated from fat tissue 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. 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
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tehran University of Medical Sciences
Full name of responsible person
Dr Masoud Younesian
Street address
6th floor, Central building of TUMS, Ghods street, Keshavarz Blv.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Tehran University of Medical Sciences
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,Tehran University of Meical Scienses
Full name of responsible person
Dr. Sudabeh Alatab
Position
Medical Doctor
Other areas of specialty/work
Street address
Urology Research Cente, Sina Hospital, Hassan-Abad Sq. Emam Khomeini St.
City
Tehran
Postal code
1136746911
Phone
+98 21 6634 8560
Fax
Email
sudabehalatab@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Gholamreza Pourmand
Position
Urologist
Other areas of specialty/work
Street address
Urology Research Center, Sina Hospital, Hassan-Abad Sq. Emam Khomeini St.
City
Tehran

Postal code
1136746911
Phone
+98 21 6634 8560
Fax
Email
gh_pourmand@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Urology Research Center,Tehran University of Medical Sciences
Full name of responsible person
Dr. Sudabeh Alatab
Position
MD
Other areas of specialty/work
Street address
Urology Research Center, Sina Hospital, Hassan-Abad Sq. Emam Khomeini St.
City
Tehran
Postal code
1136746911
Phone
+98 21 6634 8560
Fax
Email
Web page address

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