

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The secretome of pre-conditioned placenta-derived mesenchymal stem cells as an antimicrobial lock in hemodialysis patients with catheter infection: A triple-blinded randomized clinical trial

Protocol summary

Study aim

The effect of educated secretome of mesenchymal stem cells as an antimicrobial lock in hemodialysis patients with catheter infection

Design

This study will have one control group in parallel with the random block method. The type of study will be triple-blinded in phase 3 on 30 patients.

Settings and conduct

In this clinical trial study, 30 ESRD patients undergoing hemodialysis who will be referred to the Tabriz Hemodialysis and Organ Transplantation Center are randomly divided into 2 groups of 15 people, the intervention group will receive educated secretome of mesenchymal stem cells and the control group will receive vancomycin ampoule/ceftazidime+heparin for 15 days at the catheter site. The method of blinding will be triple-blinded and all the names and personal information of the patients will be coded at the time of data collection and will remain completely confidential.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Patients with end-stage kidney disease under hemodialysis for at least six month and permanent catheter infection with diagnosis of blood culture and clinical symptoms 2- Age between 18 and 80 years 3- Willingness to participate in the study 4- Under hemodialysis for two or three times a week Exclusion criteria: 1- having symptoms of severe sepsis such as decreased level of consciousness and low blood pressure 2- Having a temporary catheter 3- Having symptoms of acute thromboembolism

Intervention groups

1- Under catheter antibiotic lock with vancomycin or ceftazidime and heparin 2- Under catheter with educated secretome of mesenchymal stem cells

Main outcome variables

Examining the incidence of infection and ague

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201108049311N8**

Registration date: **2024-01-25, 1402/11/05**

Registration timing: **prospective**

Last update: **2024-01-25, 1402/11/05**

Update count: **0**

Registration date

2024-01-25, 1402/11/05

Registrant information

Name

Seyyede Mina Hejazian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3336 9331

Email address

smhjlz.biotech@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-20, 1403/01/01

Expected recruitment end date

2025-03-21, 1404/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The secretome of pre-conditioned placenta-derived mesenchymal stem cells as an antimicrobial lock in hemodialysis patients with catheter infection: A triple-blinded randomized clinical trial

Public title

The secretome of mesenchymal stem cells derived from the placenta and its secretions in the treatment of catheter infection in hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with end-stage kidney disease under hemodialysis for at least six month and permanent catheter infection with diagnosis of blood culture and clinical symptoms
Age between 18 and 80 years
Willingness to participate in the study
Under hemodialysis for two or three times a week

Exclusion criteria:

Having symptoms of severe sepsis such as decreased level of consciousness and low blood pressure
Having a temporary catheter
Having symptoms of acute thromboembolism

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Thirty men and women ESRD patients under hemodialysis will be randomly assigned into two groups receiving secretome (n=15) and vancomycin/ceftazidime+heparin (n= 15) using the random block method using blocks 4 and 6 through RAS (Random Allocation Software) and allocation ratio 1:1. To conceal the allocation, the secretome, vancomycin/ceftazidime, and heparin will be placed in opaque vials numbered from 1 to 30. Participants will receive vials numbered 1 to 30 based on the order of entering the study. Preparing the vials and numbering them will be done based on the generated random sequence by a person not involved in the research.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This study will be triple-blinded. In this way, the doctor will introduce the patients to receive secretome, vancomycin/ceftazidime, and heparin and will not be aware of the grouping. Participating volunteers will not know about receiving secretome,

vancomycin/ceftazidime, heparin, or other drugs.

Secretome, vancomycin/ceftazidime, and heparin will be placed in similar and coded vials. In addition, the placebo will be identical in appearance (shape and color), taste, and smell with secretome. In addition, due to the coding of patients and the lack of clarity in the grouping of patients, the data analyzer will be also blinded.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golgasht street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2023-05-08, 1402/02/18

Ethics committee reference number

IR.TBZMED.REC.1402.131

Health conditions studied

1

Description of health condition studied

End-stage renal disease patients under more than six month of hemodialysis treatment and diagnosis of permanent catheter infection

ICD-10 code

N18.6

ICD-10 code description

End stage renal disease

Primary outcomes

1

Description

Incidence of infection

Timepoint

15 days after the beginning of the intervention

Method of measurement

Checking the occurrence of ague (body temperature

2**Description**

The presence of suppuration and redness in the catheter site

Timepoint

15 days after the beginning of the intervention

Method of measurement

Observationally

Secondary outcomes

empty

Intervention groups**1****Description**

Control group: Under catheter antibiotic lock with vancomycin/ceftazidime+heparin (The injected dose will be determined based on blood culture results) three times a week for 15 days

Category

Treatment - Drugs

2**Description**

Intervention group: Under catheter with educated secretome (set of substances released from the cell to its surroundings) of mesenchymal stem cells retrieved from the placenta (containing 400 microgram protein/milliliter) (It will be produced through the cell culture from the placenta in the laboratory) 4 cc dissolved in albumin 20% three times a week for 15 days

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tabriz Hemodialysis and Organ Transplantation Center

Full name of responsible person

Dr. Mohammadreza Ardalan

Street address

Imam Reza hospital, Golgasht St, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3337 3992

Email**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Parviz Shahabi

Street address

Tabriz university of medical sciences, Golgasht St, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3335 7310

Email

parvizshahabi@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Farahnoosh Farnood

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Nephrology

Street address

Kidney Research Center, one floor, Imam Reza training and Research Center, Golgasht Street, Tabriz

City

Tabriz

Province

East Azarbaijan
Postal code
۵۱۶۶۶۱۴۷۵۶
Phone
+98 41 3336 9331
Email
farnoodkidney@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Abolfazl Barzegari
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Biotechnology
Street address
Stem Cell And Regenerative Medicine Institute,Tabriz
University of Medical Sciences, Tabriz, Iran
City
Tabriz
Province
East Azarbaijan
Postal code
۵۱۶۶۶۱۴۷۵۶
Phone
+98 41 3336 7929
Email
barzegari.abolfazl@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences
Full name of responsible person
Dr. Abolfazl Barzegari
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Biotechnology
Street address
Stem Cell And Regenerative Medicine Institute,Tabriz
University of Medical Sciences, Tabriz, Iran
City
Tabriz
Province
East Azarbaijan
Postal code
۵۱۶۶۶۱۴۷۵۶
Phone
+98 41 3336 7929
Email
barzegari.abolfazl@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available