

# 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

smhjl.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

above 37 °C)

ardalan34@yahoo.com

## 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

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##### Phone

+98 41 3337 3992

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## 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

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##### Province

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##### Phone

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##### 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

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##### Province

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
Dr. Abolfazl Barzegari  
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Assistant professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Medical Biotechnology  
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Stem Cell And Regenerative Medicine Institute,Tabriz  
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## Person responsible for updating data

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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