

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of reteplase on the dysfunctional permanent central venous catheter of hemodialysis

#### Protocol summary

##### Study aim

The effect of reteplase on the dysfunctional permanent central venous catheter of hemodialysis

##### Design

The clinical trial with a control group, parallel-group, double-blinded, Randomized, In 60 patients, A randomization method is used with the STATA software.

##### Settings and conduct

In this study, in patients with impaired hemodialysis central venous catheter function, 0.04 units of reteplase were injected and after 30 minutes, catheter function was evaluated. The study is performed in Ali Ibn Abitaleb Hospital in Zahedan. The patient and the analyst are unaware of the type of injectable drug.

##### Participants/Inclusion and exclusion criteria

Lack of blood flow in the catheter lumen ability to aspiration of heparin from the lumen flow rate less than 150 ml/min

##### Intervention groups

Intervention group: Injection of 2 ml of Reteplase containing 0.4 units of drug Control group: Injection of 2 ml of heparin

##### Main outcome variables

Catheter function correction

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201101049227N1**

Registration date: **2020-11-28, 1399/09/08**

Registration timing: **prospective**

Last update: **2020-11-28, 1399/09/08**

Update count: **0**

##### Registration date

2020-11-28, 1399/09/08

#### Registrant information

##### Name

Seyed Morteza Hashemizadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 54 3329 5570

##### Email address

m.hashemizadeh@zaums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

##### Expected recruitment start date

2020-12-05, 1399/09/15

##### Expected recruitment end date

2021-06-05, 1400/03/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### Scientific title

The effect of reteplase on the dysfunctional permanent central venous catheter of hemodialysis

#### Public title

The effect of reteplase on the dysfunctional permanent central venous catheter of hemodialysis

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Lack of blood flow in catheter lumen ability to aspiration of heparin from lumen flow rate less than 150 ml/min

##### Exclusion criteria:

#### Age

No age limit

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Data analyster

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

A simple randomization method is used individually with the STATA software. The software randomly determines whether patients receive heparin or reteplase.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Patients and analysts do not know which group they belong to.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of zahedan university of medical sciences

##### Street address

ZAUMS Main campus, Hesabi square, Zahedan, Sistan and Baluchestan, Iran

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9816743463

#### Approval date

2020-09-20, 1399/06/30

#### Ethics committee reference number

IR.ZAUMS.REC.1399.315

## Health conditions studied

### 1

#### Description of health condition studied

Central venous catheter

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Catheter function correction

#### Timepoint

30 minutes

#### Method of measurement

Lumen flow more than 250 ml per minute

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Injection of 2 ml of Reteplase containing 0.4 units of drug

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Injection of 2 ml of heparin

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ali ebne Abitaleb Hospital

##### Full name of responsible person

Seyed Morteza Hashemizade

##### Street address

Salamat Blvd, Persian Gulf Expressway

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9816743463

##### Phone

+98 54 3329 5715

##### Email

public@zaums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Zahedan University of Medical Sciences

##### Full name of responsible person

Vice-president for Research and Technology

**Street address**

ZAUMS Main campus, Hesabi square, Zahedan, Sistan and Baluchestan, Iran

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816743463

**Phone**

+98 54 3329 5744

**Email**

zaums.research@gmail.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Zahedan 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**

Zahedan University of Medical Sciences

**Full name of responsible person**

Seyed Morteza Hashemizadeh

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Surgery

**Street address**

Alf-ebn- abitaleb Hospital, Khalij Fars Blvd, Zahedan

**City**

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**Province**

Sistan-va-Balouchestan

**Postal code**

9816743111

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+98 54 3329 5570

**Fax**

**Email**

m.hashemizadeh@zaums.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Seyed Morteza Hashemizadeh

**Position**

Resident

**Latest degree**

Medical doctor

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Seyed Morteza Hashemizadeh

**Position**

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**Latest degree**

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**Email**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All data include the outcomes of the two groups can be published after being unidentified.

**When the data will become available and for how long**

Access to information will be granted after article publication.

**To whom data/document is available**

Data will be access by researchers from medical universities.

**Under which criteria data/document could be used**

Data will be access by researchers from medical universities.

**From where data/document is obtainable**

Dr. Seyed Moeteza Hashemizade, MD. General surgery resident, Email: dr\_hashemizadeh@yahoo.com Tell: +989128206466, Address:Ali ebne Abitaleb Hospital, Salamat Blvd, Persian Gulf Expressway, Zahedan

**What processes are involved for a request to access data/document**

The people that wanted the data should email requested the data.

**Comments**