

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 analyser

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-e-bn- abitaleb Hospital, Khalij Fars Blvd, Zahedan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743111

Phone

+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

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m.hashemizadeh@zaums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Zahedan University of Medical Sciences

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Position

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m.hashemizadeh@zaums.ac.ir

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 publishment.

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