

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

The role of Antibiotic in the prevention of surgical site infection after hemodialysis access surgery

Protocol summary

Study aim

Determining the role of antibiotics in prevention of wound infections in the surgical site of arteriovenous fistula surgery in dialysis patients

Design

Clinical trial with control group, Randomised, parallel group trial without blinded outcome assessment

Settings and conduct

The sample included dialysis patients who will undergo surgery for insertion of arteriovenous fistula in Imam Reza Hospital of Tabriz. 60 patients who will be embedded with an arteriovenous fistula will be randomly selected and 20 will receive only one pre-operative antibiotic dose, 20 will be given a preoperative dose and will continue for up to 20 days, and 20 others Antibiotics will not be given and the results of the examination of the scar tissue infection will be compared between the two groups

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients requiring fistula surgery; Surgery is done by an attending surgeon
Exclusion criteria: No consent to enter the study; Use of Immunosuppressant drugs or Chemotherapy; Active infection anywhere in the body; Prohibition of antibiotic use for any reason

Intervention groups

60 patients who will be embedded with an arteriovenous fistula will be randomly selected and 20 will receive only one pre-operative antibiotic dose, 20 will be given a preoperative dose and will continue for up to 20 days, and 20 others Antibiotics will not be given and the results of the examination of the scar tissue infection will be compared between the two groups.

Main outcome variables

Surgical site infection; type of surgery; pulmonary infection; urinary tract infection; sepsis; mortality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140203016473N10**

Registration date: **2018-06-21, 1397/03/31**

Registration timing: **prospective**

Last update: **2018-06-21, 1397/03/31**

Update count: **0**

Registration date

2018-06-21, 1397/03/31

Registrant information

Name

Farzad Kakaei

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1334 1317

Email address

fkakaei@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-21, 1397/04/30

Expected recruitment end date

2018-10-22, 1397/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The role of Antibiotic in the prevention of surgical site infection after hemodialysis access surgery

Public title

The role of Antibiotic in the prevention of surgical site infection after hemodialysis access surgery

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients requiring fistula surgery surgery is done by an attending surgeon

Exclusion criteria:

Patients who are currently in need of transplant or chemotherapy Patients who need antibiotics because of an active infection anywhere in the body, such as pneumonia or diabetic foot Patients who have been Impaired for any reason during their sterile action Patients who are forbidden to antibiotic use for any reason, such as allergy history

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Sixty patients who will be Embedded with an intravenous artery fistula will be randomly selected using WWW. Randomizer.Org.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not 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

Golgasht Ave.,Azadi Ave.,Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2018-05-21, 1397/02/31

Ethics committee reference number

IR.tbzmed.rec.1397.169

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**

wound infection

Timepoint

one week,15 days and one month after surgery

Method of measurement

Observed by the responsible physician

Secondary outcomes

empty

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

Intervention group: Only single dose of cefalexin 500 mg will be given before surgery

Category

Prevention

2**Description**

Intervention group: Single dose of cefalexin 500 mg will be given before surgery and will continue up to 10 days with a dose adjustment based on kidney failure (until removing stitches).

Category

Prevention

3**Description**

Control group: Antibiotics will not be given

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Surgery Ward of Imam Reza hospital

Full name of responsible person

Dr Farzad Kakaei

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Golgasht Ave., Azadi Ave., Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Abolqasem Jouyban

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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

Farzad Kakaei

Position

Associate Professor of General and Vascular Surgery

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Position

Associate Professor of General and Vascular Surgery

Latest degree

Subspecialist

Other areas of specialty/work

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

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available