

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

evaluating of Cotrimoxazole as an antibiotic-lock solution in prophylaxis against Dialysis Catheter-Related Bacteremia

Protocol summary

Summary

The most promising intervention for compensating kidney action in ESRD patients is hemodialysis. Using Central Venous Catheter (CVC) is common in hemodialysis patients. Having a catheter is a risk factor for inducing bacteremia among hemodialysis patients. Management of Catheter-Related Bacteremia (CRB) is just by removing catheter with systemic antibiotic administration will result in atrial access problem. An antibiotic lock technique spreads for overcoming this problem. The aim of this study is using cotrimoxazole as an antibiotic lock solution for preventing from CRB in hemodialysis patient. This study is a kind of RCT which will perform in 90 ESRD patients who have recently a temporary central line catheter and have no active infection; Evidence of exit site of infection; Cirrhosis; encephalopathy; uncontrolled cancer; Any documented sensitivity to sulfonamides family drugs as exclusion criteria. After getting permission, patients will stratified to two groups, antibiotic treated in catheter lumen as an antibiotic lock group or heparin administrated in catheter lumen as a control group. The end point of the study is CRB induction during 6 month follow up or until venous-arterial fistula maturation. CRB occurrence will compare between two groups at the end of study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201305313043N8**
Registration date: **2013-07-10, 1392/04/19**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-07-10, 1392/04/19

Registrant information

Name

Simin Dashti-Khavidaki

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Science

Expected recruitment start date

2013-04-04, 1392/01/15

Expected recruitment end date

2015-03-21, 1394/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

evaluating of Cotrimoxazole as an antibiotic-lock solution in prophylaxis against Dialysis Catheter-Related Bacteremia

Public title

Cotrimoxazole as an antibiotic-lock solution in preventing Catheter-Related Bacteremia in hemodialysis patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Recently diagnosed ESRD patients with temporary catheters. Exclusion criteria: active infection; Evidence of exit site of infection; Cirrhosis;

encephalopathy; uncontrolled cancer; Any documented sensitivity to sulfonamides family drugs.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran University of Medical Science

Street address

16 azar Avn. tehran university of medical science

City

Tehran

Postal code**Approval date**

2013-02-08, 1391/11/20

Ethics committee reference number

92-01-33-21582

Health conditions studied**1****Description of health condition studied**

CKD patients in hemodialysis

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes**1****Description**

Catheter related infection occurrence

Timepoint

during 6 month study, weekly assessment

Method of measurement

lab data from blood sample, clinical observation, follow up by questionnaire

Secondary outcomes**1****Description**

any cause of bacteremia infection

Timepoint

during 6 month study

Method of measurement

clinical observation

2**Description**

Thrombosis in catheter

Timepoint

during 6 month study

Method of measurement

clinical observation

3**Description**

any cause of hospitalization and length of hospitalization

Timepoint

during 6 month study

Method of measurement

clinical observation

4**Description**

any cause of catheter removal

Timepoint

during 6 month study

Method of measurement

clinical observation

5**Description**

any cause of mortality during study

Timepoint

during 6 month study

Method of measurement

clinical observation

6**Description**

exit-site infection

Timepoint

during 6 month study

Method of measurement

clinical observation

7

Description

occurring of antibiotic resistance (colony induction or resistance infection to antibiotic in lock solution)

Timepoint

during 6 month study

Method of measurement

lab data from blood sample

8

Description

fungal infection

Timepoint

during 6 month study

Method of measurement

lab data from blood sample

9

Description

adverse effects of antibiotic

Timepoint

during 6 month study

Method of measurement

clinical observation

10

Description

risk of unusual bleeding from catheter during dialysis

Timepoint

during 6 month study

Method of measurement

clinical observation

Intervention groups

1

Description

In experimental group: mix 2.5 ml ampule Cotrimoxazole (400/80) with 0.5 ml ampule heparin5000U then 1 ml distilled water added until total volume reach to 4 ml. In the end of dialysis section, each lumen of catheter were filled by this antibiotic solution. This action will repeat during maximum 6 month for each patient.

Category

Treatment - Drugs

2

Description

In Control group:1 ml of ampule heparin 5000 U with 3 ml distilled waterwill mix until total volume of 4 ml. In the end of dialysis section, each lumen of catheter were filled by this antibiotic solution. This action will repeat during maximum 6 month for each patient.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Dr.Efat Razeghi, nephrologist

Street address

City

Tehran

2

Recruitment center

Name of recruitment center

Emam Khomeni hospital

Full name of responsible person

Dr.Simin dashti, clinical pharماسict

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr.Simin dashti

Street address

cancer institute of tehran, Urology and Nephrology
Research Center

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact

Name of organization / entity

faculty of pharmacy, Tehran university of medical science

Full name of responsible person

Dr. Simin dashti Khadivaki

Position

assistant professor, clinical pharmacist

Other areas of specialty/work**Street address**

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Pharm. D, resident of clinical pharmacy

Other areas of specialty/work**Street address****City**

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty