Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jul 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 sensivity to sulfonamides family drugs as exclusion criateria. 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

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Simin Dashti-Khavidaki
Name of organization / entity
Tehran University of Medical Sciences
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Iran (Islamic Republic of)
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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 sensivity 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 occurence

Timepoint
during 6 month study, weekly assessment

Method of measurement
lab data from blood sample, clinical observation, follow up by questioniare

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 removement

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 distillated 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 distillated 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 pharmasict
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

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Person responsible for updating data

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Dr Azadeh Moghaddas

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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