

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of the effect of oral cotrimoxazole and topical intranasal mupirucin on staphylococcus aureus colonization in hemodialysis patients: A clinical trial

#### Protocol summary

##### Summary

The aim of this study is to compare of the effect of oral cotrimoxazole and topical intranasal mupirucin on staphylococcus aureus colonization in hemodialysis patients. Study design: After explaining the purpose of the study and obtaining the informed consent, patients will be randomly allocated into A and B groups. Randomization will be performed using random block sizes of 4. The study is randomized, single-center, phase 3 trial. Inclusion criteria : Hemodialysis patients carriers of staphylococcus. Exclusion criteria:Patients death; patients migration. Sample size:23 patients. The intervention used in the study: Oral cotrimoxazole 400 mg twice daily for 7 days. Primary outcomes: Bacterial decolonization

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016122331527N1**

Registration date: **2017-02-17, 1395/11/29**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-02-17, 1395/11/29

##### Registrant information

###### Name

Ehsan Binesh

###### Name of organization / entity

Shahroud University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 23233390433

###### Email address

binesh@shmu.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Deputy of research, Shahroud University of Medical Sciences

###### Expected recruitment start date

2017-02-19, 1395/12/01

###### Expected recruitment end date

2018-02-20, 1396/12/01

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Comparison of the effect of oral cotrimoxazole and topical intranasal mupirucin on staphylococcus aureus colonization in hemodialysis patients: A clinical trial

###### Public title

The effect of oral cotrimoxazole and topical intranasal mupirucin on staphylococcus aureus colonization in hemodialysis patients

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

Inclusion criteria : Hemodialysis patients carriers of staphylococcus. Exclusion criteria:Patients death; patients migration

###### Age

No age limit

###### Gender

Both

**Phase**

3

**Groups that have been masked**

No information

**Sample size**

Target sample size: 23

**Randomization (investigator's opinion)**

Randomized

**Randomization description****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, Vice chancellor for research,  
Shahroud University of Medical Sciences**Street address**Ethics committee, Vice chancellor for research,  
Shahroud University of Medical Sciences, 7th of Tir  
square**City**

Shahroud

**Postal code**

3613773955

**Approval date**

2015-09-29, 1394/07/07

**Ethics committee reference number**

IR.SHMU.REC.1394.117

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

Hemodialysis patients

**ICD-10 code**

Z49.1

**ICD-10 code description**

Extracorporeal dialysis

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

Bacterial decolonization

**Timepoint**

1,4 and 12 weeks after treatment

**Method of measurement**

Bacterial culture

**Secondary outcomes**

empty

**Intervention groups****1****Description**Intervention group: Oral cotrimoxazole 400 mg twice daily  
for 7 days**Category**

Treatment - Drugs

**2****Description**Control group: Topical mupirocin 2% twice daily for 5  
days**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Imam hossein hospital

**Full name of responsible person**

Dr Ehsan Binesh

**Street address**Imam Hossein Hospital, End of Ayatollah Towhidi  
avenue, Shahroud**City**

Shahroud

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**Deputy of research, Shahroud University of Medical  
Sciences**Full name of responsible person**

Mohammad hasan Emamian

**Street address**Deputy of research, Shahroud University of Medical  
Sciences, 7th of Tir square, Shahroud**City**

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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**

Deputy of research, Shahroud 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

**Name of organization / entity**

Imam Hossein Hospital, Shahroud University of  
Medical Sciences

**Full name of responsible person**

Mojgan Taleb

**Position**

Physician

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

Dr Ehsan Binesh

**Position**

Infectious disease specialist

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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*

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Imam Hossein Hospital, Shahroud University of  
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**Full name of responsible person**

Dr Ehsan Binesh

**Position**

Infectious disease specialist

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

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