

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of the effects of co-trimoxazole and co-trimoxazole plus ciprofloxacin in urinary tract infection prophylaxis in kidney transplant patients

Protocol summary

Summary

Objectives: The aim of this clinical trial study was to compare the effects of co-trimoxazole and co-trimoxazole plus ciprofloxacin for prophylaxis of urinary tract infection(UTI) in renal transplant recipients. **Design:** This clinical trial was carried out from 2014 to 2015 in Al-Zahra Hospital of Esfahan, Iran. The target population was patients undergoing kidney transplant in the center. **Setting and conduct:** The target population consists of 50 patients undergoing kidney transplantation and divided into two groups of 25 using block randomization. **Participants including major eligibility criteria:** The inclusion criteria include age over 18 years; the recipient of kidney transplant and the exclusion criteria also include concurrent use of other antibiotics in the course of investigation and withdrawal from the study. **Intervention:** In Group I, co-trimoxazole was administered with a daily dose of 160/800 mg for a period of six months as in standard protocol. In Group II, co-trimoxazole was administered daily for six months along with 250 mg ciprofloxacin every 12 hours for the first one month. The patients were followed at one, three, and six months after renal transplantation, and were treated in case of UTI. **Main outcome measures:** Questionnaires included the incidence and the time of developing of UTI after transplantation.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015120823743N1**
Registration date: **2015-12-23, 1394/10/02**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-12-23, 1394/10/02

Registrant information

Name

Farzin Khorvash

Name of organization / entity

Isfahan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Isfahan University of Medical Sciences

Expected recruitment start date

2014-08-22, 1393/05/31

Expected recruitment end date

2015-08-22, 1394/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of co-trimoxazole and co-trimoxazole plus ciprofloxacin in urinary tract infection prophylaxis in kidney transplant patients

Public title

Prophylaxis of urinary tract infection(UTI)

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age over 18 years; Consent to inclusion; The recipient of kidney transplant; Lack of recent urinary infection; Lack of Glucose 6 Phosphate Dehydrogenase(G6PD); No prior consumption of antibiotic. Exclusion criteria: Inaccessibility to the patient to determine various causes of urinary infection such as death or migration; Concurrent use of other antibiotics in the course of investigation; Withdrawal from the study; Allergic reaction to medications; Drug intolerance.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Using block randomization.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jerib Avenue, Isfahan

City

Isfahan

Postal code

Approval date

2015-04-21, 1394/02/01

Ethics committee reference number

IR.mui.rec.1394.3.264

Health conditions studied

1

Description of health condition studied

Urinary tract infection

ICD-10 code

B99,B99

ICD-10 code description

Other infectious diseases

Primary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

2

Description

-

Timepoint

-

Method of measurement

-

3

Description

Urinary tract infection

Timepoint

1,3and 6 months after intervention

Method of measurement

Questionnaire, urine analysis and urine culture

4

Description

The time of developing urinary tract infection after kidney transplant

Timepoint

1,3 and 6 months after intervention

Method of measurement

Questionnaire, urine analysis and urine culture

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

2

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Intervention group 1: In Group I, co-trimoxazole was administered with a daily dose of 160/800 mg for a period of six months as in standard protocol. (company Rose daroo)

Category

Treatment - Drugs

2

Description

Intervention group 2: In Group II, co-trimoxazole was administered daily for six months along with 250 mg ciprofloxacin every 12 hours for the first one month. Cotrimoxazole from Rose daroo company and ciprofloxacin from Farabi company

Category

Treatment - Drugs

3

Description

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital of Isfahan

Full name of responsible person

Atousa Hakamifard

Street address

Alzahra Hospital, Soffeh Avenue, Isfahan

City

Isfahan

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Recruitment center

Name of recruitment center

Alzahra Hospital of Isfahan

Full name of responsible person

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Street address

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Recruitment center

Name of recruitment center

Alzahra Hospital of Isfahan

Full name of responsible person

Atousa Hakamifard

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Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Isfahan University of Medical Sciences

Full name of responsible person

Dr Mehdi Nematbakhsh

Street address

Isfahan University of Medical Sciences, Hezar Jerib Avenue, Isfahan

City

Isfahan

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice Chancellor for research of Isfahan University of Medical Sciences

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Vice Chancellor for research of Isfahan University of Medical Sciences

Full name of responsible person

Dr Mehdi Nematbakhsh

Street address

Isfahan University of Medical Sciences, Hezar Jerib Avenue, Isfahan

City

Isfahan

Grant name

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Proportion provided by this source**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**

Isfahan University of Medical Sciences

Full name of responsible person

Atousa Hakamifard

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Assistant, infectious diseases and tropical medicine research center

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Full name of responsible person

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Position

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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