

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Comparative study of effectiveness of long term low dose antibiotic Prophylaxis in patients with recurrent UTI

Protocol summary

Summary

Urinary tract infection is a common cause of morbidity. Urinary tract should be checked for cases with recurrent UTI. Some patients have frequent UTI without any abnormality in urinary tract. In this study we will evaluate the efficacy of the long- term low-dose antibiotic prophylaxis with Cotrimoxazol and Nalidixic-acid in the patients with recurrent UTI. This study is a before and after clinical trial without control group over 100 patients with recurrent UTI who will refer to the Urology clinic, Ekbatan Hospital. These patients should not have abnormal urologic findings in clinical and para-clinical evaluations (Ultrasonography, VCUG and IVP). They will be treated by Cotrimoxazol or Nalidixic-acid in long term-low dose antibiotic prophylaxis method according to urine culture and antibiogram. Both groups will follow with urine cultures in therapeutic and 6 months follow up period. Also we will evaluate the differences between age, gender, kind of microorganism, marital status, re-infection time and number of recurrences before treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112095641N2**

Registration date: **2011-12-15, 1390/09/24**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-12-15, 1390/09/24

Registrant information

Name

Seyed Habibollah Mousavi-bahar

Name of organization / entity

Hamedan University of Medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1823 0829

Email address

shmbahar@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Hamedan University of Medical Sciences

Expected recruitment start date

2012-01-01, 1390/10/11

Expected recruitment end date

2012-09-01, 1391/06/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of effectiveness of long term low dose antibiotic Prophylaxis in patients with recurrent UTI

Public title

Treatment of recurrent urinary tract infection

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Any patient with recurrent Urinary Tract Infection, at least 3 episode of UTI during past 12 months. Exclusion criteria: Abnormal finding in physical examination or in paraclinic (ultrasonography, VCUG, Isotope Scan, IVP)

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

N/A

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Vice chancellor for research, Hamedan University of Medical Sciences

Street address

Shariati Cross Road

City

Hamedan

Postal code**Approval date**

2011-11-17, 1390/08/26

Ethics committee reference number

2007/9/35/16/P/D

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

Urinary Tract Infection

ICD-10 code

N39.0

ICD-10 code description

Urinary tract infection, site not specified

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

No Urinary Tract Infection

Timepoint

Every month for 2 months and then every 2 months for

10 months

Method of measurement

Urine Culture

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

Recurrence of Urinary Tract Infection

Timepoint

Every month for 2 months and then every 2 months for 10 months

Method of measurement

Urine Culture

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

After properly treating the current UTI, we will start longterm lowdose antibiotic (Cotrimoxazole or Nalidixic acid) based on urine culture and antibiogram. One tablet per night for adults and weight adjusted dose for children.

Category

Treatment - Drugs

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

Ekbatan Hospital

Full name of responsible person

Seyed Habibollah Mousavi-bahar

Street address

Urology Ward

City

Hamedan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Heidar Tavilani

Street address

Opposit to Mardom Park

City

Hamedan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Hamedan 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**

Hamedan University of Medical sciences

Full name of responsible person

Seyed Habibollah Mousavi-bahar

Position

Associate Prof.

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

Urology Ward, Ekbatan Hospital

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Full name of responsible person

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Position

Associate Prof. in Urology

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

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Web page address**Person responsible for updating data****Contact****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