

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

A comparative study of single dose versus 3 days regime of Ampicillin, Ccephalosporin, and Nitrofurantoin in treatment of Cystitis in pregnancy referred to Imama Reza Hospital.

Protocol summary

Summary

This study will be done with aim to compare investigation of a single dose treatment regimens and three-day Ampicillin, Cephalosporins and Nitrofurantoin in the treatment of cystitis in pregnant women refer to Imam Reza Hospital . In this study, patients with more than 20 weeks gestational age and singleton pregnant with cystitis symptoms will be enrolled in the study and patients who are sensitive to study antibiotics are excluded. This is non-blinded clinical trial. 246 Of 20-35 years pregnant women with a diagnosis of pregnant cystitis that refer to Imam Reza Hospital in Kermanshah will be selected and randomly will assigned to six groups of 41 persons. Beginning of the study urine culture tests will be done for each patient. In the first group, treated will be done with penicillin single dose (2 g) and in the second group, three-day treatment Ampicillin (250 mg). The third experimental group will receive single dose of cephalosporin (2 g) and fourth experimental group will receive three-day cephalosporin (250 mg). The fifth experimental group Nitrofurantoin single dose (200 mg) will given and sixth experimental group will receive three-day Nitrofurantoin (100 mg). In the three-day treatments, all three groups will given antibiotics every 6 hours. Then the 7 to 10 days after completion of treatment, urine tests will be done for the three groups for the second time and information related to patients cystitis, completed in the checklist. Inclusion criteria: 1 gravidity women; Age 35-20 years Exclusion criteria: A mother's sensitivity to antibiotics

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016072814333N54**
Registration date: **2016-08-26, 1395/06/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-08-26, 1395/06/05

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

Expected recruitment start date

2016-08-15, 1395/05/25

Expected recruitment end date

2016-08-15, 1395/05/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of single dose versus 3 days regime of Ampicillin, Ccephalosporin, and Nitrofurantoin in

treatment of Cystitis in pregnancy referred to Imama Reza Hospital.

Public title

Comparison of antibiotic treatment regimens in the treatment of pregnant women cystitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1 gravidity women; Age 35-20 years; No history of systemic diseases and certain medications; Gestational age above 20 weeks and singleton pregnant with cystitis symptoms (dysuria who, frequent urination, suprapubic pain, polyuria); Patients who UA and UC tests will carried out for them and bacteriuria and pyuria will reported for them. Exclusion criteria: Pregnant women with complicated pregnancy or access to them is not possible; Chronic and incurable diseases or blood diseases, liver or diabetic; Patients who have taken antibiotics in the past three weeks, or history of positive kidney disease and bladder; Pregnant women with symptoms of fever, chills, CVA and signs of pyelonephritis or are sensitive to the study antibiotics.

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **246**

Randomization (investigator's opinion)

N/A

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 of Kermanshah University of Medical Sciences

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Postal code

Approval date

2016-06-22, 1395/04/02

Ethics committee reference number

KUMS.REC.1395.221

Health conditions studied

1

Description of health condition studied

pregnancy

ICD-10 code

Z34.8

ICD-10 code description

Supervision of other normal pregnancy

Primary outcomes

1

Description

Pregnancy cystitis

Timepoint

Beginning of the study, 7 to 10 days after completion of treatment

Method of measurement

Based on the experimental results

Secondary outcomes

empty

Intervention groups

1

Description

In the first group, treated will be done with penicillin single dose (2 g).

Category

Treatment - Drugs

2

Description

The fifth experimental group Nitrofurantoin single dose (200 mg) will given

Category

Treatment - Drugs

3

Description

In the second group, three-day treatment will be done with Ampicillin (250 mg) and will given antibiotics every 6 hours.

Category

Treatment - Drugs

4

Description

The third experimental group will receive single dose of cephalosporin (2 g)

Category

Treatment - Drugs

5

Description

Fourth experimental group will receive three-day cephalosporin (250 mg) and will given antibiotics every 6 hours.

Category

Treatment - Drugs

6

Description

Sixth experimental group will receive three-day Nitrofurantoin (100 mg) and will given antibiotics every 6 hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Dr. Elham sadate Alavimoghadam

Street address

Emam Reza Hospital, Parastar Boulevard

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person

Koroush Hamzehee

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

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, Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Negin Rezavand

Position

Professor of Obstetrics and Gynecology

Other areas of specialty/work

Street address

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Person responsible for updating data

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Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Elham sadate Alavimoghadam

Position

PhD student of Obstetrics and Gynecology

Other areas of specialty/work

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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