Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A comparative study of single dose versus 3 days regime of Ampicillin, Ccephalosporin, and Nitrofurantoin in treatment of Cystitis in pregnancy reffered 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 0f 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

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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 reffered 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
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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
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Person responsible for updating data

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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