Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jul 2026

Comparison of the efficacy of Cefazolin and Naproxen with Cefazolin only in the treatment of cellulitis

Protocol summary

Study aim

Comparison of the efficacy of Cefazolin and Naproxen with Cefazolin only in the treatment of cellulitis

Design

A double-blind randomized Clinical trial with a control group, with parallel groups, on 60 patients.

Settings and conduct

This study was performed on patients with cellulitis admitted to Labbafinejad hospital, Tehran, Iran in 2020. After obtaining informed consent, eligible patients were randomly divided into two groups A and B. Intervention group (B) received Cefazolin (1-1.5 g intravenously every 8 hours) and Naproxen (500 mg orally every 12 hours). And control group (A) received Cefazolin only (1-1.5 g intravenously every 8 hours). Then, an assessor evaluated the response of patients in each group to the medications prescribed. In this study, patients and the assessor of response to therapy did not know the names of patients in the control and intervention groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Hospitalized patients with a diagnosis of cellulitis; Age over 18 years; Willingness to participate in this clinical trial. Exclusion criteria: Allergy to Penicillin, Cefazolin or Naproxen; Pregnant women; Immunodeficiency; Patients with mucocutaneous diseases; Patients with kidney diseases; Patients with vascular catheters; Patients suspected of having septic arthritis or osteomyelitis; Patients with infected diabetic foot ulcers; Bite or the presence of a foreign body in the wound; Perianal cellulitis; Injecting substance abuse; Hospitalization during the last three months; Chronic hemodialysis patients.

Intervention groups

Group A was treated with Cefazolin alone. Group B was treated with Cefazolin in combination with Naproxen.

Main outcome variables

Body temperature; Improvement of clinical symptoms; Hospitalization time average; Epigastric pain; Itching; Diarrhea; skin rash.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201204049598N1**
Registration date: **2021-09-08, 1400/06/17**
Registration timing: **retrospective**

Last update: **2021-09-08, 1400/06/17**
Update count: **0**

Registration date

2021-09-08, 1400/06/17

Registrant information

Name

Sadaf Saket

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

dasdd272@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-19, 1398/12/29

Expected recruitment end date

2021-03-20, 1399/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of Cefazolin and Naproxen with Cefazolin only in the treatment of cellulitis

Public title
Effect of Naproxen in the treatment of cellulitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Hospitalized patients with a diagnosis of cellulitis Age over 18 years Willingness to participate in this clinical trial
Exclusion criteria:
Allergy to Penicillin, Cefazolin or Naproxen Pregnant women Immunodeficiency Patients with mucocutaneous diseases Patients with kidney diseases Patients with vascular catheters Patients suspected of having septic arthritis or osteomyelitis Patients with infected diabetic foot ulcers Bite or the presence of a foreign body in the wound Perianal cellulitis Injecting substance abuse Hospitalization during the last three months Chronic hemodialysis patients
Age
From **18 years** old
Gender
Both

Phase
0
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Using a table of random numbers, patients are randomly divided into two groups of intervention and control, and receive the medication of the same group.
Blinding (investigator's opinion)
Double blinded
Blinding description
First, written informed consent is obtained from patients. Based on the list prepared by the researcher, the clinician prescribes two types of medication regimens for patients: the intervention group receives Cefazolin (1-1.5 gram intravenously every 8 hours) and Naproxen (500 milligram orally every 12 hours), and the control group receives Cefazolin only (1-1.5 gram intravenously every 8 hours). An individual, then evaluates the clinical outcome. In this study, patients and clinical outcome assessors are not aware of the names of the intervention and control groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research ethics committees of school of medicine; Shahid Beheshti university of medical sciences
Street address
School of medicine of Shahid Beheshti university of medical sciences, Koudakyar Ave., Daneshjoo Blvd., Velenjak.
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Province
Tehran
Postal code
1983969411
Approval date
2020-01-05, 1398/10/15
Ethics committee reference number
IR.SBMU.RETECH.REC.1398.86

Health conditions studied

1

Description of health condition studied
Cellulitis
ICD-10 code
L03
ICD-10 code description
Cellulitis and acute lymphangitis

Primary outcomes

1

Description
Erythema
Timepoint
Before the intervention, 2, 3, and 5 to 7 days after the start of the intervention
Method of measurement
Trained doctor report

2

Description
Warmth
Timepoint
Before the intervention, 2, 3, and 5 to 7 days after the start of the intervention
Method of measurement
Trained doctor report

3

Description
Tenderness
Timepoint
Before the intervention, 2, 3, and 5 to 7 days after the start of the intervention
Method of measurement
Trained doctor report

4

Description
Body temperature
Timepoint
Before the intervention, 2, 3, and 5 to 7 days after the start of the intervention
Method of measurement
Using a mercury thermometer

5

Description
Reduce exudate secretion from the wound
Timepoint
Before the intervention, 2, 3, and 5 to 7 days after the start of the intervention
Method of measurement
Trained doctor report

6

Description
Hospitalization duration
Timepoint
Before the intervention, 2, 3, and 5 to 7 days after the start of the intervention
Method of measurement
Medical record

Secondary outcomes

1

Description
Epigastric pain
Timepoint
Before the intervention, 2, 3, and 5 to 7 days after the start of the intervention
Method of measurement
Trained doctor report

2

Description
Diarreha
Timepoint
Before the intervention, 2, 3, and 5 to 7 days after the start of the intervention
Method of measurement
Trained doctor report

3

Description
Itching
Timepoint
Before the intervention, 2, 3, and 5 to 7 days after the start of the intervention
Method of measurement
Trained doctor report

4

Description
Skin rash
Timepoint
Before the intervention, 2, 3, and 5 to 7 days after the start of the intervention
Method of measurement
Trained doctor report

Intervention groups

1

Description
Intervention group: The intervention group received Cefazolin (1.5-1 g intravenously every 8 hours) and Naproxen (500 mg orally every 12 hours) until the end of hospitalization. The drugs used are the product of Dr. Abidi.
Category
Treatment - Drugs

2

Description
Control group: The control group received Cefazolin only (1.5-1 g intravenously every 8 hours) until the end of hospitalization.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Labbafinejad hospital
Full name of responsible person
Sadaf Saket
Street address
Labbafinejad hospital, 9th Boostan St., Pasdaran St., Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Infectious diseases and tropical medicine research center
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School of medicine of Shahid Beheshti university of medical sciences, Koudakyar Ave., Daneshjoo Blvd., Velenjak.
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Email
idtmrc@sbmu.ac.ir
Web page address
http://idtmrc.sbmu.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Sadaf Saket
Position
Medical doctor
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Only the outcome data can be published.
When the data will become available and for how long
Access starts 6 months after the article is published
To whom data/document is available
Researchers working in academic institutions
Under which criteria data/document could be used
After the article is published, the data is available
From where data/document is obtainable
The first author of the article
What processes are involved for a request to access data/document
After sending an email to the first author of the article, the data will be available within four weeks.
Comments