

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

+98 21 2231 3681

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.

City

Tehran

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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1666663111

Phone

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Email

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

Street address

School of medicine of Shahid Beheshti university of medical sciences, Koudakyar Ave., Daneshjoo Blvd., Velenjak.

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1983969411

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Email

idtmrc@sbmu.ac.ir

Web page address

<http://idtmrc.sbm.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

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Person responsible for updating data

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Position

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Email

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