

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Comparison of the outcome of low dose and high-dose corticosteroid in the treatment of granulomatous mastitis

Protocol summary

Study aim

The aim of current study is to evaluate the effect of high and low dose prednisolone on the symptoms of patients with granulomatous mastitis.

Design

Clinical trial study, with parallel groups, double blinded, randomized

Settings and conduct

Thirty female patients with granulomatous mastitis were randomly assigned to two groups of 15 patients. First group received prednisolone 5 mg daily for two months and second group received prednisolone 50 mg for 3 days, then 25 mg for 3 days, then 12.5 mg for 3 days and 5 mg daily afterwards till the end of two months. The outcome and response to treatment was compared between groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women with Idiopathic granulomatous mastitis, age > 18 years. Exclusion criteria: Pregnant women, women with non-idiopathic granulomatous mastitis, infectious diseases and allergies and contraindications to use corticosteroids.

Intervention groups

Intervention group 1: Low dose prednisolone.
Intervention group 2: High dose prednisolone.

Main outcome variables

Response to treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120605009948N8**

Registration date: **2019-10-13, 1398/07/21**

Registration timing: **retrospective**

Last update: **2019-10-13, 1398/07/21**

Update count: **0**

Registration date

2019-10-13, 1398/07/21

Registrant information

Name

Majid Montazer

Name of organization / entity

Tabriz University of Medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-19, 1396/01/30

Expected recruitment end date

2019-04-19, 1398/01/30

Actual recruitment start date

2017-09-06, 1396/06/15

Actual recruitment end date

2019-02-19, 1397/11/30

Trial completion date

2020-02-19, 1398/11/30

Scientific title

Comparison of the outcome of low dose and high-dose corticosteroid in the treatment of granulomatous mastitis

Public title

the outcome of low dose and high-dose corticosteroid in the treatment of granulomatous mastitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women with Idiopathic granulomatous mastitis age > 18 years
Exclusion criteria:
Pregnant women women with non-idiopathic granulomatous mastitis women with infectious diseases and allergies contraindications to use corticosteroids

Age

From **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients are simply randomized to two groups through random number table; received a special code and are treated with own group treatment.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding will be as patients will randomly allocated to two treatment groups and each patient will receive sealed envelope named A or B including the defined treatment and patients will not be aware of the contents of the each envelope. Physician responsible for labeling the envelopes will not interfere with the study and other physician will asses the treatment outcome unaware of the contents of the envelopes. Data will present to statistical analyzers as A & B groups. They will be blinded about the intervention and placebo groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

1476651666

Approval date

2017-03-02, 1395/12/12

Ethics committee reference number

IR.TBXMED.REC.1397.592

Health conditions studied

1

Description of health condition studied

granulomatous mastitis

ICD-10 code

N61

ICD-10 code description

Inflammatory disorders of breast

Primary outcomes

1

Description

Response to treatment

Timepoint

Before and two months after treatment

Method of measurement

physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Prednisolone will be administered 5 mg daily for two months

Category

Treatment - Drugs

2

Description

Intervention group: Prednisolone will be administered 50 mg per day for 3 days, 25 mg for 3 days, 12.5 mg for 3 days and 5 mg daily afterwards till the end of two months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Majid Montazer Bavi

Street address

Imam Reza Hospital, Golgasht St., Azadi Ave

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Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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

Tabriz University of Medical Sciences

Full name of responsible person

Abolghasem Jouyban

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

Yes

Title of funding source

Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Mahid Montazer Bavi

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Majid Montazer Bavi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Not applicable
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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
We have not yet set a conclusion
When the data will become available and for how long
We have not yet set a conclusion
To whom data/document is available
We have not yet set a conclusion
Under which criteria data/document could be used
We have not yet set a conclusion
From where data/document is obtainable
We have not yet set a conclusion
What processes are involved for a request to access data/document
We have not yet set a conclusion
Comments