

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparison of three types of treatments in patients with Idiopathic Granulomatous Mastitis

Protocol summary

Study aim

Comparison of the type of new treatments for idiopathic granulomatous mastitis

Design

The double-blind randomized control trial

Settings and conduct

We decided to do a randomized, clinical trial for the most common treatments of this disease. We have located randomly the patients to one of the three treatment groups at the University Jihad, Breast Cancer Research Center and receive the informed consent form, and then follow them for 12 months, and ultimately respond to the treatment and side effects of the drug are compared in 3 groups. We will accurately record each patient's profile in a questionnaire. Laboratory and pathological characteristics are also evaluated in Kermanshah. Patients and researchers are also blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Female patients with Idiopathic Granulomatous Mastitis, age > 18 years Exclusion criteria: Patients with previous treatment, pregnant women, women without satisfaction; and women with infectious diseases and allergies

Intervention groups

Group 1: Some doctors believe that the disease does not need to be treated at a warm, red, and massive stage, but if it leads to an abscess, it will empty the abscess and give antibiotics. Group 2: A group of other doctors believes that the treatment of this disease is using corticosteroids such as prednisolone. In this group, the daily dose of 5mg / m2 decreases from dose to drug discontinuation. Group 3: In this group, prednisone is given high doses (4 mg / m2) twice a week, and rescue folic acid on days when the methotrexate tablet is not used for 18 months.

Main outcome variables

Response to treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160101025791N3**

Registration date: **2019-03-04, 1397/12/13**

Registration timing: **retrospective**

Last update: **2019-03-04, 1397/12/13**

Update count: **0**

Registration date

2019-03-04, 1397/12/13

Registrant information

Name

Masoud Sadeghi

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 83 3842 5822

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-28, 1397/08/06

Expected recruitment end date

2018-11-28, 1397/09/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of three types of treatments in patients with Idiopathic Granulomatous Mastitis

Public title

Treatments of Idiopathic Granulomatous Mastitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Female patients Patients without systematic diseases

Exclusion criteria:

Pregnant women Women with a history of breast cancer in the family

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **150**

More than 1 sample in each individual

Number of samples in each individual: **50**

Group 1: Some doctors believe that the disease does not need to be treated at a warm, red, and massive stage, but if it leads to an abscess, it depletes the abscess and give antibiotics. Group 2: Because this is an autoimmune disease, another group of doctors believe that the treatment of this disease is using corticosteroids such as prednisolone. Group 3: Many patients can not continue prednisolone, and these patients use the combination of prednisolone and methotrexate.

Randomization (investigator's opinion)

Randomized

Randomization description

We is located four-piece papers (to the total number of patients) in a small box. On each paper, the number of each group has been written. The patient is asked to remove randomly one of the papers and read the number. The patient is not given any information about the type of treatments and the groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participant and Clinical Clinician (Physician) are kept blind. The study is double-blind. Participants are placed in each group respectively. The investigator (physician assistant) collects information. Researcher prepares the paper. The doctor evaluates the outcome.

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

Vice - Chancellery of Research & Technology Affairs, building No.2, Shahid Beheshti Blvd., Kermanshah

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2018-10-10, 1397/07/18

Ethics committee reference number

IR.KUMS.REC.1397.564

Health conditions studied

1

Description of health condition studied

Idiopathic Granulomatous Mastitis

ICD-10 code

L92

ICD-10 code description

Granulomatous disorders of skin and subcutaneous tissue

Primary outcomes

1

Description

Response to treatment

Timepoint

Before and after 6 months of intervention

Method of measurement

ELISA kit

Secondary outcomes

1

Description

White blood cell

Timepoint

Before and after 6 months of intervention

Method of measurement

LeukoChek test kit

Intervention groups

1

Description

Group 1: Some doctors believe that the disease does not need to be treated at a warm, red, and massive stage, but if it leads to an abscess, it will empty the abscess and give antibiotics. This is the best remedy.

Category

Treatment - Drugs

2

Description

Group 2: Because of the autoimmune disease, another group of doctors believes that the treatment of this disease is using corticosteroids such as prednisolone. In this group, the daily dose of 5mg / m2 decreases from dose to drug discontinuation.

Category

Treatment - Drugs

3

Description

Group 3: Many patients can't continue prednisolone, they use prednisolone + immunosuppressants (such as methotrexate) in these patients. In this group, prednisone is given high doses (4 mg / m2) twice a week orally and rescue folic acid on days when the methotrexate tablet is not used for 18 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Motamed Cancer Institute

Full name of responsible person

Safa Najafi

Street address

No. 146, Southern Gandhi Early, Vanak Square,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Vice-Chancellery of Research & Technology Affairs of
Kermanshah University of Medical Science

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Vice-Chancellery of Research & Technology Affairs,
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farid_n32@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Mazaher Ramezani

Position

Associate professor

Latest degree

Medical doctor

Other areas of specialty/work

Pathology

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Undecided - It is not yet known if there will be a plan to make this available

When the data will become available and for how long

Undecided - It is not yet known if there will be a plan to make this available

To whom data/document is available

Undecided - It is not yet known if there will be a plan to make this available

Under which criteria data/document could be used

Undecided - It is not yet known if there will be a plan to make this available

From where data/document is obtainable

Undecided - It is not yet known if there will be a plan to make this available

What processes are involved for a request to access data/document

Undecided - It is not yet known if there will be a plan to make this available

Comments