

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

A Randomized Controlled Trial Study on the Effectiveness of Local Injection combined with with Systemic therapy and Topical Steroids injection alone or Systemic therapy alone in the Treatment of Idiopathic Granulomatous Mastitis

Protocol summary

Study aim

This study aims to evaluate the Effectiveness of Local Steroid Injection alone, in comparison with Steroid injection Combined with Systemic therapy vs. Systemic therapy alone in the Treatment of Idiopathic Granulomatous Mastitis

Design

A randomized clinical trial with three intervention parallel groups, that 90 patients will be enrolled in phase 2. Random Allocation Software will use for block randomization.

Settings and conduct

This study will be conducted in the Breast Diseases Research Center. Patients will be allocated into one of the three groups. Group one will be treated with Local steroid injection followed by systemic oral corticosteroid and MTX as systemic treatment. Group two will be treated with systemic oral corticosteroid and MTX as systemic treatment. Group three will be treated with Local steroid injection by the physician once a week.

Participants/Inclusion and exclusion criteria

Idiopathic Granulomatous Mastitis female patients aged between 18-65 who require not a surgical treatment without other malignancy or breast cancer.

Intervention groups

All Patients will treat with 2-week oral antibiotics (Ciprofloxacin, Metronidazole).The patients will allocate in three study groups, randomly. Group one, will be treated with local steroid injection by the physician once a week for one to four times (betamethasone LA injection) and followed by oral corticosteroid(Prednisolon) and MTX as systemic treatment. Group two will include oral corticosteroid and MTX as systemic treatment. Group three will be treated with Steroid injection to the breast by the physician once a week for one to four times.

Main outcome variables

Disappearance of inflammatory signs, closure of fistula orifices,and skin erosions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200608047694N1**

Registration date: **2020-07-21, 1399/04/31**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-21, 1399/04/31**

Update count: **0**

Registration date

2020-07-21, 1399/04/31

Registrant information

Name

Vahid Zangouri

Name of organization / entity

Country

Iran (Islamic Republic of)

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zangouri@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-23, 1399/03/03

Expected recruitment end date

2021-04-21, 1400/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Randomized Controlled Trial Study on the Effectiveness of Local Injection combined with with Systemic therapy and Topical Steroids injection alone or Systemic therapy alone in the Treatment of Idiopathic Granulomatous Mastitis

Public title

Effectiveness of Local Injection (Bethametasone LA) combined with Systemic therapy (Methotrexate and Prednisolone) and Topical Steroids injection alone or Systemic therapy alone in the Treatment of Idiopathic Granulomatous Mastitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Female patients with Idiopathic Granulomatosis Mastitis
Female patients aged 18-65
Female patients with Idiopathic Granulomatosis Mastitis which require non-surgical treatment

Exclusion criteria:

Female patients with Idiopathic Granulomatosis Mastitis who has abcess
Female patients with Idiopathic Granulomatosis Mastitis which require surgical intervention or has breast cancer or other malignancy

AgeFrom **18 years** old to **65 years** old**Gender**

Female

Phase

2-3

Groups that have been masked*No information***Sample size**Target sample size: **90****Randomization (investigator's opinion)**

Randomized

Randomization description

In order to avoid selection bias all the patients allocated to three groups by blocked randomization. It ensures that participants are assigned to groups with equal probability. In this study the size of each block is equal and consist of three patients. The treatments are randomly allocated to the experimental units inside each block and all treatments appear at least once in each block

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 Shiraz University of Medical Sciences

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Karimkhan Zand Avenue ,Namazee square, shahid motahari clinic.Breast diseases research center

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Postal code

۷۱۳۴۸-۷۱۴۷۳۷

Approval date

2020-05-23, 1399/03/03

Ethics committee reference number

IR.SUMS.MED.REC.1399.096

Health conditions studied**1****Description of health condition studied**

Idiopathic Granulomatous Mastitis

ICD-10 code

N61

ICD-10 code description

Inflammatory disorders of breast

Primary outcomes**1****Description**

The disappearance of inflammatory signs

Timepoint

All Patients will be followed weekly in first month and then monthly for 5 months for detect symptoms

Method of measurement

The clinical response is categorized into completely healed, inadequately healed, stable, worsened, or relapsed that will be evaluated by surgeon.

2**Description**

Closure of fistula orifices

Timepoint

All Patients will be followed weekly in the first month and then monthly for 5 months to detect symptoms

Method of measurement

The clinical response is categorized into completely healed, inadequately healed, stable, and worsened that will be evaluated by the surgeon.

3

Description

Disappearance of skin erosion

Timepoint

All Patients will be followed weekly in the first month and then monthly for 5 months to detect symptoms

Method of measurement

The clinical response is categorized into completely healed, inadequately healed, stable, and worsened that will be evaluated by the surgeon.

Secondary outcomes

1

Description

granulomatous mastitis recurrence in the Ipsilateral breast

Timepoint

All Patients will be exam by surgeon and sonography will be done for all of them at the last month of follow up

Method of measurement

The occurrence of Granulomatosis Mastitis will be assessed by the surgeon and doing sonography.

Intervention groups

1

Description

Group one (N=30, systemic therapy plus local steroid injection) will be treated with Local steroid injection to the breast by the physician once a week for one to four times (betamethasone LA injection, each injection contains betamethasone Acetate at 3 mg and betamethasone disodium phosphate 3 mg/ml) and followed by systemic oral corticosteroid and Methotrexate (MTX) as systemic treatment (MTX 10 mg PO per week for 5 months and prednisolone 1mg/kg/day for the first month, then taper to 5 mg/day in 4 months following months)

Category

Treatment - Drugs

2

Description

Intervention group 2: Group two (N=30) will include systemic oral Corticosteroid and MTX as systemic treatment (MTX 10 mg PO per week for 2 months and Prednisolone 1mg/kg/day for the first month, then taper to 5 mg/day in 4 months following months)

Category

Treatment - Drugs

3

Description

Intervention group3: Group three (N=30) will be treat with Local steroid injection to the breast by the physician once a week for one to four times (Betamethasone LA injection, each injection contains Betamethasone Acetate

at 3 mg and Betamethasone disodium phosphate 3 mg/ml)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Breast Diseases Research Center

Full name of responsible person

Vahid Zangouri

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
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Position
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Person responsible for updating data

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is 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

Information about the main outcome of the study will be shared while maintaining the confidentiality of patient information.

When the data will become available and for how long

Data will be available, 3 months after publication

To whom data/document is available

Researchers affiliated with academic institutions

Under which criteria data/document could be used

The use of data from this study in the form of higher and more complete sample size studies is not prohibited

From where data/document is obtainable

Breast Diseases Research Center, Shahid Motahhrai
Clinic affiliated to shiraz university of medical sciences

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

Referring to the Breast Diseases Research center and after applying the request, the request will be evaluated

in the approved meetings.

Comments