Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)
Phone
+98 71 3612 1000
Email address
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 (Methotraxate 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
Age
From **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
Street address
Karimkhan Zand Avenue ,Namazee square, shahid motahhari clinic.Breast diseases research center
City
SHIRAZ
Province
Fars
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
Street address
Karimkhan Zand Avenue, Namazi Square,Shahid Motahari Clinic
City
Shiraz
Province
Fars
Postal code
7134814336
Phone
+98 71 3612 1000
Email
zangouri@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Vahid Zngouri
Street address
Karimkhan Zand Avenue ,Namazi Square.Shahid Motahhari Clinic
City
Shiraz
Province
Fars
Postal code
7134814336
Phone
+98 71 3612 1000
Email
zangouri@sums.ac.ir
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

Vahid Zangouri

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

Karim khan ZAnd, Namazi Square. Shahid motahhari Clinic

City

shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3612 1000

Email

zangouri@sums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Vahid Zangouri

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

karimkhan zand avenue.namzai square. shahid motahhari clinic

City

shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3612 1000

Email

zangouri@sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Yasin Krami

Position

consultant

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

karimkhan zand avenue.namzai square.shahid motahhari clinic

City

shiraz

Province

Fars

Postal code

7134814336

Phone

009836121000

Email

yasinkarami@gmail.com

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,3months 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