

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

A Randomized Clinical Trial to Evaluate the Efficacy of Systemic Treatment in Combination with Topical steroid versus Systemic Treatment Alone in Managing Skin Involvement of Patients with Idiopathic Granulomatous Mastitis.

Protocol summary

Study aim

This study aims to evaluate the efficacy of systemic treatment in combination with topical steroids versus systemic treatment alone in managing skin involvement of patients with Idiopathic Granulomatous Mastitis

Design

A randomized clinical trial with three intervention parallel groups, 40 patients will be enrolled in phase 2. Random Allocation Software will be used for block randomization.

Settings and conduct

This study will be conducted in the Breast Diseases Research Center in Shiraz. Patients will be allocated into one of the two groups. Group one will be treated with oral systemic treatment. Group two will be treated with oral systemic treatment followed by topical steroids.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Female patients with idiopathic granulomatous mastitis between the ages of 18 and 65 who do not have diabetes, hypertension, other autoimmune diseases, breast cancer, or other malignancies that do not require surgical treatment. Exclusion criteria: Lack of consent to participate in the study and grade I disease severity

Intervention groups

All Patients will be treated with 2-week oral antibiotics (Ciprofloxacin, Metronidazole). The patients will be allocated to two study groups, randomly. Group one will be treated with systemic oral corticosteroid and MTX as systemic treatment. Group two will be treated with systemic oral corticosteroids and MTX as systemic treatment followed by daily usage of topical steroids (Fluocinolone ointment twice a day for the first 5 days of the week and mometasone ointment twice a day for two days of the weekend).

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: **IRCT20230822059222N1**

Registration date: **2023-10-07, 1402/07/15**

Registration timing: **prospective**

Last update: **2023-10-07, 1402/07/15**

Update count: **0**

Registration date

2023-10-07, 1402/07/15

Registrant information

Name

Aliyeh Ranjbar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3481 4336

Email address

aliyeh.ranjbar@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-22, 1402/07/30

Expected recruitment end date

2023-11-21, 1402/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Randomized Clinical Trial to Evaluate the Efficacy of Systemic Treatment in Combination with Topical steroid versus Systemic Treatment Alone in Managing Skin Involvement of Patients with Idiopathic Granulomatous Mastitis.

Public title

Topical steroid in Managing Skin Involvement of Patients with Idiopathic Granulomatous Mastitis.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

A confirmed diagnosis of idiopathic granulomatous mastitis (IGM) based on histopathological examination The patients should require non-surgical treatment for their condition The severity of involvement should be grade II, III, or IV according to the modified classification of Yuan et al Absent of breast carcinoma or other malignancies or systemic diseases such as vasculitis, collagen vascular disease, or sarcoidosis Absent of a risk factor for steroid therapy, such as hypertension or diabetes mellitus

Exclusion criteria:

Lack of consent to participate in the study The severity of the conflict is grade 1

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

Female

Phase

2

Groups that have been masked*No information***Sample size**Target sample size: **40****Randomization (investigator's opinion)**

Randomized

Randomization description

In this study, we will employ stratified block randomization to ensure an even distribution of patients by disease grade. We will enroll 12 patients with grade 2, 16 patients with grade 3, and 12 patients with grade 4. Then, we will use a block randomization method with blocks containing 4 patients each to randomly assign patients to either the intervention or control group within each disease grade.

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

Breast Disease Research Center, Shahid Motahari Clinic, Namazi Square, Karimkhan Zand Street

City

Shiraz

Province

Fars

Postal code

۷۱۳۴۸-۷۱۴۷۳۷

Approval date

2023-08-14, 1402/05/23

Ethics committee reference number

IR.SUMS.MED.REC.1402.225

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, worsened, or relapsed that will be evaluated by 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, worsened, or relapsed that will be evaluated by surgeon.

Secondary outcomes

1

Description

Resolution of skin involvement

Timepoint

One year after starting the treatment

Method of measurement

Assessed by the surgeon

Intervention groups

1

Description

Intervention group: The systemic treatment regimen will be adjusted based on the severity of the disease, as follows:- Grade II: Oral prednisolone with a starting dose of 30-20 mg/day, tapered over 6-8 weeks. In addition to prednisolone, 5 mg of oral methotrexate will be administered weekly.- Grade III: Oral prednisolone with a starting dose of 50-40 mg/day, tapered over 20-24 weeks. In addition to prednisolone, 15 mg of oral methotrexate will be administered weekly.- Grade IV: Oral prednisolone with a starting dose of 60-50 mg/day, tapered over 20-30 weeks. In addition to prednisolone, 15 mg of oral methotrexate will be administered weekly. For the first two weeks of treatment, a combination of antibiotics (ciprofloxacin 500 mg every 12 hours and metronidazole every 8 hours) will be used. All patients will receive daily administration of calcium-D and folic acid supplements to prevent osteoporosis and folate deficiency. Topical treatment: The topical treatment will consist of the application of Fluocinolone ointment twice a day for the first 5 days of the week and Mometasone ointment twice a day for two days of the weekend for 6 months.

Category

Treatment - Drugs

2

Description

Control group: The systemic treatment regimen will be adjusted based on the severity of the disease, as follows:- Grade II: Oral prednisolone with a starting dose of 30-20 mg/day, tapered over 6-8 weeks. In addition to prednisolone, 5 mg of oral methotrexate will be administered weekly.- Grade III: Oral prednisolone with a

starting dose of 50-40 mg/day, tapered over 20-24 weeks. In addition to prednisolone, 15 mg of oral methotrexate will be administered weekly.- Grade IV: Oral prednisolone with a starting dose of 60-50 mg/day, tapered over 20-30 weeks. In addition to prednisolone, 15 mg of oral methotrexate will be administered weekly. For the first two weeks of treatment, a combination of antibiotics (ciprofloxacin 500 mg every 12 hours and metronidazole every 8 hours) will be used. All patients will receive daily administration of calcium-D and folic acid supplements to prevent osteoporosis and folate deficiency.

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

Shahid Motahari Clinic, Namazi Square, Karimkhan Zand Street

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

Shahid Motahari Clinic, Namazi Square, Karimkhan Zand Street

City

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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

Associate professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

Shahid Motahari Clinic, Namazi Square, Karimkhan Zand Street

City

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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

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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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

Aliyeh Ranjbar

Position

General practitioner

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Breast Disease Research Center, Shahid Motahari Clinic, Namazi Square, Karimkhan Zand Street

City

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Province

Fars

Postal code

7134814336

Phone

+98 71 3612 1000

Email

Aliyeh.ranjbar@yahoo.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, 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