Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Local steroid injection versus systemic steroid therapy in the inflammatory phase of idiopathic granulomatous mastitis: a clinical trial randomized controlled study

Protocol summary

Study aim
To compare the efficacy and adverse effects of intralesional triamcinolone injection with systemic prednisolone treatment in women with uncomplicated idiopathic granulomatous mastitis

Design
Open label randomized controlled clinical trial with two parallel groups and a sample size of 60 patients. Patients will be allocated in a 1:1 ratio using block randomization with a block size of 4

Settings and conduct
The study will be conducted on eligible patients referred to the Shahid Beheshti Hospital of Kashan. After obtaining written informed consent and recording baseline data, patients will be allocated to one of the two groups and followed at months 1, 2, and 3 for treatment response and adverse effects. Blinding of patients and the clinical team is not feasible

Participants/Inclusion and exclusion criteria
Participants are women with pathologically confirmed idiopathic granulomatous mastitis and a negative polymerase chain reaction test for tuberculosis; patients with complicated mastitis, evidence of tuberculosis or breast malignancy, contraindication to corticosteroids, pregnancy, or lactation will not be enrolled

Intervention groups
The control group will receive 20 mg of oral prednisolone daily. The intervention group will receive intralesional triamcinolone injection according to the extent of involvement, up to a maximum dose of 200 mg. Both groups will receive 40 mg of pantoprazole daily

Main outcome variables
Treatment response at the end of the third month which is defined as improvement or resolution of clinical signs and symptoms accompanied by reduction or resolution of the lesion on ultrasonography compared with baseline

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260509069303N1**
Registration date: **2026-06-14, 1405/03/24**
Registration timing: **prospective**

Last update: **2026-06-14, 1405/03/24**
Update count: **0**

Registration date
2026-06-14, 1405/03/24

Registrant information

Name
Zahra Afshari

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 5366 5181

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-07-01, 1405/04/10

Expected recruitment end date
2026-11-01, 1405/08/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Local steroid injection versus systemic steroid therapy in the inflammatory phase of idiopathic granulomatous mastitis: a clinical trial randomized controlled study

Public title
Systemic and local steroid injections in granulomatous mastitis.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Women with idiopathic granulomatous mastitis confirmed by pathological diagnosismastitis Patients classified as group 2 according to the Turkish clinical classification including uncomplicated granulomatous Negative PCR test for tuberculosis Willingness to participate in the study and signing the written informed consent form Ability to attend the scheduled follow up visits

Exclusion criteria:
Presence of complicated granulomatous mastitis including abscess fistula or skin ulcer at the time of enrollment Evidence of breast malignancy or other known causes of granulomatous mastitis Definite contraindication to corticosteroid therapy Recent use of systemic corticosteroids or immunosuppressive drugs for the same disease Uncontrolled diabetes uncontrolled hypertension or severe active infection Pregnancy or lactation at the time of enrollment

Age
From **18 years** old

Gender
Female

Phase
1

Groups that have been masked

- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the unit of randomization is each eligible patient. After assessment of the inclusion and exclusion criteria and obtaining written informed consent, patients will be randomly allocated in a 1:1 ratio to either the systemic treatment group receiving oral prednisolone or the local injection group receiving intralesional triamcinolone. Block randomization with a block size of 4 will be used. The random allocation sequence will be generated by an independent person who is not involved in patient treatment, using statistical software or a random number table. Allocation concealment will be maintained using sequentially numbered, opaque, sealed envelopes. The envelope for each patient will be opened only after final enrollment and recording of baseline data. Stratified randomization will not be used in this study.

Blinding (investigator's opinion)
Single blinded

Blinding description
Due to the obvious difference between the treatment methods, including oral prednisolone and intralesional triamcinolone injection, blinding of participants, clinical caregivers, the radiologist performing the injection, and the principal investigator is not feasible. Therefore, this study will be conducted as an open label randomized controlled clinical trial. Outcomes will be assessed based on clinical evaluation, ultrasonographic findings, and recording of predefined objective adverse events. To reduce bias, data will be recorded in a standardized checklist and, if feasible, statistical analysis will be performed using coded study groups so that the data analyst remains unaware of the allocated intervention.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research ethics committee of faculty of medicine and faculty of dentistry - Kashan university of med

Street address
Pezeshk Blvd. - Qotb Blvd.

City
Kashan

Province
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Postal code
8715973474

Approval date
2026-04-19, 1405/01/30

Ethics committee reference number
IR.KAUMS.MEDNT.REC.1405.008

Health conditions studied

1

Description of health condition studied
idiopathic granulomatous mastitis

ICD-10 code
L92.8

ICD-10 code description
Other granulomatous disorders of the skin and subcutaneous tissue

Primary outcomes

1

Description

Treatment response at the end of the third month is defined as at least 50 percent reduction in the size of the breast lesion on ultrasonography accompanied by improvement or resolution of clinical signs of breast inflammation compared with baseline

Timepoint

At baseline before starting the intervention and at the end of the third month after starting the intervention

Method of measurement

The outcome will be measured using clinical breast examination and breast ultrasonography. In the clinical examination, pain, redness, swelling, mass, abscess, or fistula will be assessed, and on ultrasonography, the size of the breast lesion will be compared with baseline

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in this group will receive intralesional triamcinolone injection according to the extent and depth of the breast lesion. After local anesthesia, 40 mg of triamcinolone will be injected for each lesion and each involved layer, including superficial, intermediate, and deep layers. The maximum total dose of triamcinolone in each injection session will be 200 mg. The injection will be performed by an experienced radiologist under ultrasonographic guidance. To prevent gastrointestinal adverse effects, patients will receive 40 mg of oral pantoprazole daily.

Category

Treatment - Drugs

2

Description

Intervention group: Patients in this group will receive 20 mg of oral prednisolone daily, administered in two divided doses. Treatment will be continued according to the study protocol and the patient’s clinical response until the end of the three month follow up period. To prevent gastrointestinal adverse effects, patients will receive 40 mg of oral pantoprazole daily. Patients will be followed for treatment response and adverse effects at the end of the first, second, and third months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti hospital, Kashan

Full name of responsible person

Hamed Pahlavani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Gholamali Hamidi

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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

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Zahra Afshari

Position

General Surgery Resident

Latest degree
Medical doctor
Other areas of specialty/work
General Surgery
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not 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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
All data will be shareable after individuals are de-identified.
When the data will become available and for how long
6 months after publication of the article
To whom data/document is available
De identified individual participant data and study documents will be considered for access only after a written request from researchers affiliated with universities, research centers, or scientific institutions. Access to the data by commercial or industrial individuals or companies is not planned.
Under which criteria data/document could be used
The data and documents may be used only for scientific and research purposes related to the study topic, secondary analyses, systematic reviews, meta analyses, or planning future studies. Submission of a research proposal, approval by the study team, protection of confidentiality, no attempt to identify participants, and commitment to use the data only for the approved purpose are required. Any publication based on the data must acknowledge the source study and comply with research ethics principles.
From where data/document is obtainable
Requests for access to data or documents should be submitted in writing to the principal investigator or study investigator. The applicant should provide name and institutional affiliation, purpose of the request, type of required data or documents, and the proposed analysis plan. Contact information: Principal investigator Zahra Afshari, email address: Z-afshari@kaums.ac.ir
What processes are involved for a request to access data/document
After receiving a written request, the request will be reviewed regarding the research purpose, scientific affiliation of the applicant, type of requested data or documents, and compliance with ethical considerations.

If necessary, additional information or a confidentiality agreement will be requested from the applicant. After approval by the study team, de identified individual participant data or available documents will be provided to the applicant. The result of the review will usually be communicated to the applicant within a maximum of 30 working days.

Comments