Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effects of three types of non-surgical treatments in the management of idiopathic Granulomatous Mastitis

Protocol summary

Study aim

Determining and comparing the effect of three non-surgical treatments of Idiopathic Granulomatous Mastitis

Design

Design: Phase 3, multi-center, clinical trial on 147 patients who will be randomly divided into 3 groups. Patients will be assigned to three groups based on the city in which they live. Patients will be followed up every three weeks for three months. At the end of three months, if the clinical symptoms are completely cured, they will be considered as successful treatment. If the disease progresses or the symptoms do not improve will be considered as "refractory".

Settings and conduct

This multicenter study will be conducted in different cities. Since the project is implemented in several centers across the country, all of the centers will be coordinated by the project manager. the project manager will be in regular contact with all participating centers and will assess the correct completion of forms and on-time visits of patients. She will report regularly to the head of the research project. The study variables will be recorded in special checklists during each visit. Blinding: None.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pathological diagnosis of Granulomatous Mastitis Exclusion criteria: fungal infection, concomitant tuberculosis, systemic symptoms including fever (not due to superinfection of mastitis granulomatosis), polyarthritis or polyarthralgia, generalized lymphadenopathy

Intervention groups

Group 1: Prednisolone Group 2: Colchicine Group 3: Naproxen and topical Plantago major ointment

Main outcome variables

Ulcer; Fistula; Erythema size

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100706004329N10**
Registration date: **2021-05-07, 1400/02/17**
Registration timing: **prospective**

Last update: **2021-05-07, 1400/02/17**
Update count: **0**

Registration date

2021-05-07, 1400/02/17

Registrant information

Name
Sadaf Alipour
Name of organization / entity
Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
00982177888751 - 00982177883195
Email address
salipour@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2023-05-22, 1402/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effects of three types of non-surgical treatments in the management of idiopathic Granulomatous Mastitis

Public title
Non-surgical treatment of Granulomatous Mastitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Pathological diagnosis of Granulomatous Mastitis
Exclusion criteria:
Fungal infection Tuberculosis Systemic symptoms including fever (not due to super infection of Granulomatous Mastitis) Polyarthritis or Polyarthralgia Generalized lymphadenopathy
Age
No age limit
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **147**
Randomization (investigator's opinion)
Not randomized
Randomization description
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 Tehran University of Medical Sciences
Street address
Qods St, Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2021-04-21, 1400/02/01
Ethics committee reference number
IR.TUMS.SINAHOSPITAL.REC.1400.012

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
Ulcer
Timepoint
Before the intervention and then every three weeks to three months
Method of measurement
Examination

2

Description
Fistula
Timepoint
Before the intervention and then every three weeks to three months
Method of measurement
Examination

3

Description
Size of Erythema
Timepoint
Before the intervention and then every three weeks to three months
Method of measurement
Examination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: They will take Prednisolone 15 mg daily, and in case of treatment refractory, they will take Prednisolone at a dose of 30 mg.
Category
Treatment - Drugs

2

Description
Intervention group 2: They will take 1 mg of colchicine twice a day, and in case of treatment refractory, they will take Prednisolone at a dose of 30 mg.

Category
Treatment - Drugs

3

Description
Intervention group: They will take Naproxen 250 mg twice daily (for 2 weeks only) and topical Plantago major ointment, and in case of treatment-refractory, the steroid will be injected into the lesion

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Arash women's hospital

Full name of responsible person
Dr Sadaf Alipour

Street address
No. 162 Alley (Abdul Majid), Shahid Baghdarnia Street (North Rashid), Shahid Bagheri Highway, Resalat Highway, Tehran, Iran

City
Tehran

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Web page address
http://arash.tums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr Mohammad Ali Sahraian

Street address
6th floor, Central University, Qods St, Keshavarz Blv, Tehran, Iran

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Email
resdeputy@tums.ac.ir

Web page address
http://vcr.tums.ac.ir/

Grant name

Grant code / Reference number

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

Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Sadaf Alipour

Position
Professor

Latest degree
Subspecialist

Other areas of specialty/work
General Surgery

Street address
Arash Women 's Hospital, Rashid Ave, Resalat Highway, Tehranparse,Tehran.Iran

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Web page address

Person responsible for scientific

inquiries

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Person responsible for updating data

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
The research team has not yet decided about the publication of participants' data.

Study Protocol
Undecided - It is not yet known if there will be 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
Not applicable