

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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), polyarthrititis 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) Polyarthritits 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

##### Province

Tehran

##### Postal code

1653915981

##### Phone

+98 21 7788 3283

##### Fax

+98 21 7788 3196

##### Email

salipour@sina.tums.ac.ir

##### 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

##### City

Tehran

##### Province

Tehran

##### Postal code

1417653761

##### Phone

+98 21 8838 8988

##### Fax

+98 21 8838 8988

##### 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

##### City

Tehran

##### Province

Tehran

##### Postal code

1653915981

##### Phone

+98 21 7771 9922

##### Fax

##### Email

salipour@sina.tums.ac.ir

##### Web page address

## Person responsible for scientific

## **inquiries**

### **Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

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**Email**

salipour@sina.tums.ac.ir

**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