Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jul 2026

Assessment of the effect of local imiquimod on idiopathic granulomatous mastitis

Protocol summary

Study aim
Determining the effect of topical application of Imiquimod in the treatment of resistant granulomatous mastitis

Design
A Phase two Clinical trial, without a control group, on 5 patients.

Settings and conduct
Setting: Arash Women's Hospital 5 eligible patients with refractory granulomatous will be included into the study after obtaining written consent and the desired intervention will be performed on them as described in the relevant section. Randomization and Blinding: Since there is only one intervention group, randomization and blinding are not applicable.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Granulomatous mastitis resistant to common treatments Exclusion criteria: Wounds or abscesses, allergy to Imiquimod

Intervention groups
The intervention group includes 5 patients with refractory granulomatous mastitis who will receive Imiquimod cream topically, once a day until the regression of lesions (up to two months).

Main outcome variables
Erythema size; Number of fistulas; Mass size or tissue stiffness

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100706004329N11**
Registration date: **2021-09-07, 1400/06/16**
Registration timing: **prospective**

Last update: **2021-09-07, 1400/06/16**
Update count: **0**

Registration date
2021-09-07, 1400/06/16

Registrant information

Name
Sadaf Alipour

Name of organization / entity
Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-23, 1400/07/01

Expected recruitment end date
2022-05-22, 1401/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Assessment of the effect of local imiquimod on idiopathic granulomatous mastitis

Public title
imiquimod for treatment of granulomatous mastitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of granulomatous mastitis based on

pathological examination of lesions Refractory to common treatments including anti-inflammatory drugs, corticosteroids or colchicine and antibiotics after one month of treatment Presence of erythema or fistula

Exclusion criteria:

Presence of active ulcers Abscess History of use and allergy to imiquimod Cases where the disease involves only a deep mass and has no superficial manifestations

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **5**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Imam Khomeini Hospital Complex- Tehran University of Medical Sciences

Street address

Keshavarz Blvd., Imam Khomeini Hospital Complex

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Tehran

Province

Tehran

Postal code

1417653761

Approval date

2021-08-04, 1400/05/13

Ethics committee reference number

IR.TUMS.IKHC.REC.1400.180

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

Erythema

Timepoint

At the beginning of the study (before the intervention) and then once a week until the end of the intervention

Method of measurement

Examination

2

Description

ulcers

Timepoint

At the beginning of the study (before the intervention) and then once a week until the end of the intervention

Method of measurement

Examination

3

Description

fistula

Timepoint

At the beginning of the study (before the intervention) and then once a week until the end of the intervention

Method of measurement

Examination

4

Description

mass

Timepoint

At the beginning of the study (before the intervention) and then once a week until the end of the intervention

Method of measurement

Examination

5

Description

Tissue thickness

Timepoint

At the beginning of the study (before the intervention) and then once a week until the end of the intervention

Method of measurement

Examination

6

Description

number of lesions

Timepoint

At the beginning of the study (before the intervention) and then once a week until the end of the intervention

Method of measurement

Examination

7

Description

size of lesions

Timepoint

At the beginning of the study (before the intervention) and then once a week until the end of the intervention

Method of measurement

Examination

Secondary outcomes

1

Description

Drug Side effects

Timepoint

At the end of the study

Method of measurement

Check list

Intervention groups

1

Description

Intervention group: imiquimod topical cream will be applied once a day, topically on the whole lesion. imiquimod is an imidazo-quinolin and its structural formula includes 3-(2-Methylpropyl)-3,5,8-triazatricyclo[7.4.0.02,6]trideca-1(9),2(6),4,7,10,12-hexaen-7-amine. It acts as a regulator of the immune response. Imiquimod 5% cream under the brand name of Aldara is available in the market in the form of 250 ml sachets. In this treatment, imiquimod cream is applied topically on the lesion. The method of use is that a size of a fingertip of cream is placed on the finger and rubbed and spread by the patient herself on the lesion. The cream will be applied once a day. The duration of the intervention depends on the response. In case of no response, the treatment will be discontinued after 2 weeks and if there is a response, it will continue until complete recovery for a maximum of two months. The response status of the lesions will be checked every week and will be recorded in each referral. If the drug response is seen, it lasts until complete recovery, but up to a maximum of two months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash Women 's Hospital

Full name of responsible person

Sadaf Alipour, Professor of Surgery

Street address

Arash Women 's Hospital, Rashid Ave, Resalat Highway, Tehranparse

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Mohammad Ali Sahraian

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

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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

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
D.r Sadaf Alipour
Position
Professor of Surgery
Latest degree
Subspecialist
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
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
Undecided - It is not yet known if there will be a plan to make this available