

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Comparison of Relapse in Idiopathic Granulomatous Mastitis patients treated either by pharmaceutical or surgical approaches

Protocol summary

Summary

This study compares concomitant application of Azithromycin and corticosteroids with surgical approach usage in Idiopathic Granulomatous Mastitis (IGM) patients. The study is a kind of non-randomized clinical trial, which was implemented without blindness. The target population comprised women whose IGM disease was substantiated. Inclusion criteria involved women with mastitis whose diseases as IGM were substantiated through biopsy, but they were not treated via any interventional method. Exclusion criteria were composed of dissuasion of individuals for treatment procedures. In medical group, twenty individuals were selected via simple consecutive sampling. However, thirty nine individuals, who had operation of partial mastectomy in their medical history, were retrospectively selected as control group. In pharmaceutical groups, at first, patients were treated by concomitant application of Azithromycin (250 milligram twice per week) and Prednisolone (40 milligram daily). Afterwards the protocol suggested Prednisolone treatment for eight weeks (40 mg per day) then it was tapered for 6 months. Recurrence of mass in pharmaceutical trial, via physical examination, was followed monthly.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013123015999N1**
Registration date: **2014-01-27, 1392/11/07**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-01-27, 1392/11/07

Registrant information

Name

Roya Taleban

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Isfahan Infectious and Tropical Diseases Research Center

Expected recruitment start date

2012-05-11, 1391/02/22

Expected recruitment end date

2012-11-12, 1391/08/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Relapse in Idiopathic Granulomatous Mastitis patients treated either by pharmaceutical or surgical approaches

Public title

Relapse Rate in an Inflammatory Disease of Breast Treated by Pharmaceutical and Surgical Approaches

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Women who are well documented Idiopathic Granulomatous Mastitis (IGM) patients via pathological finding, IGM patient being not treated

Exclusion criteria: Dissuasion of individuals for treatment procedures.

Age

From **7 years** old to **65 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **59**

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 Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq.

City

Isfahan

Postal code

Approval date

2012-05-10, 1391/02/21

Ethics committee reference number

291163

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

relapse

Timepoint

Patients were monthly examined for 15 months (from initiation of the intervention to 6 months after cessation of the intervention)

Method of measurement

physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention : Azithromycin and Prednisolone concomitant application of Azithromycin (250 milligram twice per week) and Prednisolone (40 milligram daily). Afterwards the protocol suggested Prednisolone treatment for eight weeks (40 mg per day) then it was tapered for 6 months

Category

Treatment - Drugs

2

Description

control:Partial mastectomy

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra University Hospital

Full name of responsible person

Street address

Al-Zahra University Hospital, Sofeh Blvd., Isfahan, Iran.

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Isfahan University of Medical Sciences

Full name of responsible person

Dr. Peyman Adibi

Street address

Vice chancellor for research, Isfahan University of

Medical Sciences, hezar-jarib St., Azadi Sq., Isfahan

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research Isfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Roya Taleban

Position

Resident of Community Medicine

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty