

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effectiveness of Topical Curcumin for Treatment of Mastitis in Breastfeeding Women: a randomized, double-blind, placebo-controlled clinical trial.

Protocol summary

Summary

The aim of our study is to assess anti-inflammatory effects of curcumin in preparations for topical use comparing to placebo in patients with lactational mastitis. Individuals in one group will be treated with a topical curcumin cream as an anti-inflammatory agent (curcumin-treated group). The topical Curcumin Cream-200mg per pump (Neurobiologix, Texas, USA) will be prescribed with the following method: patients will be asked to apply one pump of the cream to the affected breast each 8 hours for a course of treatment which lasted 72 hours. On the other group, individuals will be prescribed with a topical moisturizer cream as the placebo (placebo group) and the treatment course are similar to the curcumin-treated group. Moreover, prior to randomization, all of the patients will be taught for effective milk removal for 24 hours as the standard first line of treatment. In order to obtain the values for breast tension, pain and erythema all of the participants will be evaluated clinically by one expert staff nurse before starting treatment. After treatment are initiated, patients will be reevaluated by the same staff nurse 3 times with intervals of 24 hours in order to record changes of inflammation severity index. The patients will be randomized using a computer-based random digit generator based on the registration number of the patients (on the order of refer). Study creams will be allocated in separate packs blinded and labeled using a four-digit code. The information regarding which codes correspond to what treatment will be maintained by the consulting statistician.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014051811375N4**

Registration date: **2014-05-26, 1393/03/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-05-26, 1393/03/05

Registrant information

Name

pouya farhadi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1625 4206

Email address

farhadip@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2011-10-01, 1390/07/09

Expected recruitment end date

2012-04-30, 1391/02/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Topical Curcumin for Treatment of Mastitis in Breastfeeding Women: a randomized, double-

blind, placebo-controlled clinical trial.

Public title

Effectiveness of Topical Curcumin for Treatment of Mastitis in Breastfeeding Women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Breast feeding women with aged 20-40 years old; Breast feeding women with inflammatory symptoms of breast during lactation; Patients with inflammation scored 8-14 based of inflammation severity index. Exclusion Criteria: women with breast abscess, breast engorgement, blocked duct and galactocelle; Individuals who has a previous history of mastitis, recent trauma to the affected breast, breast surgery, inflammatory skin diseases and recurrent mastitis; Mothers who has taken systemic antibiotics in the recent 2 months.

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences

Street address

Shiraz university of medical sciences Building, 7th floor, Zand Ave.

City

Shiraz

Postal code

Approval date

2011-05-07, 1390/02/17

Ethics committee reference number

CT-P-90-5163

Health conditions studied

1

Description of health condition studied

Mastitis

ICD-10 code

N61

ICD-10 code description

Inflammatory disorders of breast

Primary outcomes

1

Description

Inflammation severity

Timepoint

Before and 24h, 48h, 72h after intervention

Method of measurement

Inflammation severity index

Secondary outcomes

1

Description

Pain Severity

Timepoint

Before and 24h, 48, 72h after intervention

Method of measurement

Visual analogue scale

Intervention groups

1

Description

Individuals in intervention group will be treated with a topical curcumin cream (200mg per pump) as an anti-inflammatory agent. Patients will be asked to apply one pump of the cream to the affected breast each 8 hours for a course of treatment which lasted 72 hours.

Category

Treatment - Drugs

2

Description

In placebo group, individuals will be prescribed with a topical moisturizer cream as the placebo (placebo group) and the treatment course is similar to the intervention group

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Breastfeeding clinic of Shiraz university of Medical Sciences

Full name of responsible person**Street address****City**

Shiraz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Midical Sciences

Full name of responsible person

Basir Hashemi

Street address

Shiraz university of medical sciences, Zand Ave

City

Shiraz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz University of Midical 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**

Shiraz University of Medical Sciences

Full name of responsible person

Dr.Pouya Farhadi

Position

General Physician

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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