

# 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

**Other areas of specialty/work****Street address**

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Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Raha Afshariani

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**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*