

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Study on effects of topical *Nigella sativa* seed oil in treatment of cyclic mastalgia.

#### Protocol summary

##### Summary

Objective: Study on effects of topical *Nigella sativa* seed oil in treatment of cyclic mastalgia. Study population: Women with cyclic mastalgia attending the Yazd Shahid Rahnemoon hospital (Iran). Sample size: 150 patients. Inclusion criteria: Iranian outpatient females with cyclic mastalgia, patients aged 25-45 years; patients with regular menstrual cycles; patients with cyclic mastalgia diagnosis based on history of cyclic mastalgia for at least the past 3 consecutive cycles, patients with pain duration of at least 7 days per month and mastalgia severity score greater than 4 on a 10 centimeter visual analogue scale requiring pharmacotherapy. Exclusion criteria: Patients receiving hormone therapy or hormonal contraceptive; patients with irregular menstrual cycles; patients with history of breast and endometrial cancer, hysterectomy and bilateral oophorectomy; pregnant women; breast-feeding women; women planning pregnancy; women with serious health problems. Intervention: Each of the *Nigella sativa* seed oil, diclofenac and placebo gels is separately applied 2 times daily to the site of breast pain in a group of 50 women with cyclic mastalgia. At the end of the study, the drugs effects on the 10 centimeter visual analog pain score are determined and compared with each other.

#### General information

##### Acronym

SETNSOTCM

##### IRCT registration information

IRCT registration number: **IRCT201506132288N8**

Registration date: **2015-06-25, 1394/04/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-06-25, 1394/04/04

##### Registrant information

###### Name

Saeed Kianbakht

###### Name of organization / entity

Iranian Academic Center for Education, Culture and Research Institute of Medicinal Plants

###### Country

Iran (Islamic Republic of)

###### Phone

+98 26147640109

###### Email address

kianbakht@imp.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

ACECR Institute of Medicinal Plants

##### Expected recruitment start date

2014-04-26, 1393/02/06

##### Expected recruitment end date

2014-10-31, 1393/08/09

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Study on effects of topical *Nigella sativa* seed oil in treatment of cyclic mastalgia.

##### Public title

Study on effects of black seed oil in treatment of cyclic mastalgia

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Iranian outpatient females with cyclic

mastalgia, patients aged 25-45 years; patients with regular menstrual cycles; patients with cyclic mastalgia diagnosis based on history of cyclic mastalgia for at least the past 3 consecutive cycles, patients with pain duration of at least 7 days per month and mastalgia severity score greater than 4 on a 10 centimeter visual analogue scale requiring pharmacotherapy. Exclusion criteria: Patients receiving hormone therapy or hormonal contraceptive; patients with irregular menstrual cycles; patients with history of breast and endometrial cancer, hysterectomy and bilateral oophorectomy; pregnant women; breast-feeding women; women planning pregnancy; women with serious health problems.

**Age**

From **25 years** old to **45 years** old

**Gender**

Female

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **150**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Triple blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Yazd University of Medical Sciences

**Street address**

Boulevard of Shohadayeh Gomnan

**City**

Yazd

**Postal code**

2317356371

**Approval date**

2014-04-09, 1393/01/20

**Ethics committee reference number**

1217

**Health conditions studied****1****Description of health condition studied**

Mastalgia

**ICD-10 code**

N64.4

**ICD-10 code description**

Mastodynia

**Primary outcomes****1****Description**

Pain severity score

**Timepoint**

Before, 1 and 2 months after beginning of the intervention

**Method of measurement**

10 centimeter visual analog scale

**Secondary outcomes****1****Description**

Adverse drug reactions

**Timepoint**

1 and 2 months after beginning of the intervention

**Method of measurement**

Patient report

**Intervention groups****1****Description**

Nigella sativa seed oil gel is used at the dose of 600 mg topically on the site of breast pain twice daily in 50 patients for 2 months

**Category**

Treatment - Drugs

**2****Description**

Diclofenac gel is used at the dose of 20 mg topically on the site of breast pain twice daily in 50 patients for 2 months

**Category**

Treatment - Drugs

**3****Description**

Placebo gel is used topically on the site of breast pain twice daily in 50 patients for 2 months

**Category**

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Shahid Rahnemoon hospital

**Full name of responsible person**

Dr. Mohammad Hosein Mirshamsi

**Street address**

Farrokhi street

**City**

Yazd

Town, 55th Kilometer of Tehran-Gazvin Freeway

**City**

Karaj

**Postal code**

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**Phone**

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+98 26 3476 4021

**Email**

skianbakht@yahoo.comskianbakht@gmail.com

**Web page address**

www.imp.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

ACECR Institute of Medicinal Plants

**Full name of responsible person**

Dr. Saeed Kianbakht

**Street address**

Pouleh kordan, Supa boulevard, ACECR complex

**City**

Karaj

**Grant name**

1252

**Grant code / Reference number**

1252

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

Yes

**Title of funding source**

ACECR Institute of Medicinal Plants

**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**

ACECR Institute of Medicinal Plants

**Full name of responsible person**

Dr. Saeed Kianbakht

**Position**

Ph.D. in pharmacology, assistant professor of the department of pharmacology and applied medicine in

**Other areas of specialty/work**

**Street address**

Institute of Medicinal Plants, Research Complex of the ACECR, End of Kavosh Boulevard, Kavosh Research

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

ACECR Institute of Medicinal Plants

**Full name of responsible person**

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**Other areas of specialty/work**

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## Person responsible for updating data

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**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*