

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

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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**

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Person responsible for updating data

Contact

Name of organization / entity

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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