Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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; pregnanct women; brest-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; pregnanct women; brest-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
Boulevar 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

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 Town, 55th Kilometer of Tehran-Gazvin Freeway
City
Karaj
Postal code
2378965473
Phone
+98 26 3476 4010
Fax
+98 26 3476 4021
Email
skianbakht@yahoo.comskianbakht@gmail.com
Web page address
www.imp.ac.ir

Person responsible for scientific 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 Town, 55th Kilometer of Tehran-Gazvin Freeway
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skianbakht@yahoo.comskianbakht@gmail.com
Web page address
www.imp.ac.ir

Person responsible for updating data

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
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skianbakht@yahoo.comskianbakht@gmail.com
Web page address
www.imp.ac.ir

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