Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Nigella sativa oill and Vitex agnus on severity mastalgia during pregnancy

Protocol summary

Summary

This study is a clinical trial to evaluate effect of Nigella Sativa Oill and Vitex agnus on severity mastalgia during pregnancy with two intervention groups and a placebo group . This study is a triple blind. Samples of human society consists of women 15 to 49 years with cyclic mastalgia who is referred to the Breast Cancer Research. Breast pain before the intervention, after the intervention, using a ruler pain (visual pain scale) and McGill questionnaire will be evaluated. Women with inclusion criteria were randomized to an intervention groups and a control group. An intervention group , 10 ml (two tablespoons) of syrup containing 5 mL of Nigella Sativa Oil mixed with honey and water will use daily. Another experimental group, 10 ml (two tablespoons) mixed with water and honey syrup containing 60 drops Vitagnus will use daily. The placebo group, 10 ml (two tablespoons) of syrup containing 1 ml of edible oil mixed with water and honey para Finn will be given for 3 months.The placebo group, 10 ml (two tablespoons) of syrup containing 1 ml of Minral Oil mixed with water and honey will be given for 3 months (Daily per person in each group will receive two ml honey daily). Form completed by the participants will be recorded daily pain every day. pain scores after the intervention will compare to pain scores before the intervention. Improvement in pain intensity than before the intervention and the outcome will be the case.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104304785N3**
Registration date: **2015-02-02, 1393/11/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-02-02, 1393/11/13

Registrant information

Name
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sicences

Expected recruitment start date

2014-08-09, 1393/05/18

Expected recruitment end date

2015-03-09, 1393/12/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Nigella sativa oill and Vitex agnus on severity mastalgia during pregnancy

Public title

Comparison of Nigella sativa oill and Vitex agnus on breast pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: women who have literacy; women who are between 49-15 years; women who have cyclic mastalgia; women have not with suspicious lesions or ulcers on ultrasound or mammography over the last year; visual pain scale score (vas) is more than3; women have not with a history of breast surgery; women experience physical and mental illness are not known; women who not use of any medication such as analgesics, anti-inflammatory drugs and other treatments for mastalgia during the last two months; women who do not Addiction to drugs; women who do not consume alcohol; women who do not smoke.
Exclusion Criteria: women with mastalgia who are allergic to medications; women with mastalgia who are not willing to continue to work and are not taking drug; women do not have medication during every month for more than 2 days and 4 days of intermittent; women who become pregnant during the study; Women who need to take painkillers regularly.

Age

From **15 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **108**

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

Tehran University of Medical Siences

Street address

6th floor, Central Building, Ghods Street, Keshavarz Street.

City

Tehran

Postal code

Approval date

2014-06-14, 1393/03/24

Ethics committee reference number

93-01-28-25215-111782

Health conditions studied

1

Description of health condition studied

Communication of Nigella sativa oill and Vitex agnus on severity mastalgia durig the female reproductive.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Severity mastalgia

Timepoint

2 months before the intervention, and 3 months after intervention

Method of measurement

Visual analog pain scale and McGill questionnaire

Secondary outcomes

1

Description

Black Seed Oil impact of the intervention group

Timepoint

3 months after intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

Black Seed is one of the intervention groups

Category

Treatment - Drugs

2

Description

The second intervention group is taking Vitex agnus.

Category

Treatment - Drugs

3

Description

The third group is the Placebo

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Breast Cancer Research

Full name of responsible person
Seiede Tahereh Mirmolaei

Street address
Tehran University of Medical Sciences, Faculty of Nursing and Midwifery, Nusrat Street, Tohid Square, Tehran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Siences

Full name of responsible person
Deputy of chanceller for research

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City
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Grant name

Grant code / Reference number

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

Title of funding source
Tehran University of Medical Siences

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
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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