

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

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

#### Protocol summary

##### Summary

This study is a clinical trial to evaluate effect of Nigella Sativa Oil 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

Seyedeh Tahereh Mirmolaei

###### Name of organization / entity

Nursing and Midwifery Faculty - Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

00982166927171- 00982166937120

###### Email address

mirmolaei@sina.tums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Tehran University of Medical Scinces

##### 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 oil and Vitex agnus on severity mastalgia during pregnancy

##### Public title

Comparison of Nigella sativa oil 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 than 3; 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 Sciences

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

Communication of Nigella sativa oil and Vitex agnus on severity mastalgia during 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.

**City**

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Deputy of chancellor for research

**Street address**

Deputy of chancellor for reseach, 6th floor, Central Building, Ghods Street, Keshavarz Street.

**City**

Tehran

**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 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Ameneh Sotoodeh Moridani

**Position**

M.S. Midwifery student

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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**

Seyedeh Tahereh Mirmolaei

**Position**

Member faculty of Tehran University, master degree midwifery

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

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## Person responsible for updating data

### Contact

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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*