

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Comparison of the effect of sesame oil and almond oil on preventing the striae gravidarum

#### Protocol summary

##### Study aim

Determination comparison of the effect of sesame oil and almond oil on preventing the striae gravidarum.

##### Design

A randomized clinical trial, with parallel group and blinded, design of 134 patients, enrolled between July 2014 and February 2018, and Followed up to 20 weeks for each pregnant women.

##### Settings and conduct

Double blinded sampling was done in public health centers in the north, south, east, west and downtown in Kashan. The samples were randomly divided into sesame oil, almond oil and control groups. The intervention groups use oils and the control group did not use any substance.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: The current gestational age is 16 weeks, no history of abortion at gestational age 16 weeks or more, singleton pregnancy, being Iranian, nulliparous Exclusion criteria: use of other substances for the prevention or treatment of striae, presence of striae, having Cushing's disease and diabetes, alcoholic, BMI >30

##### Intervention groups

The sesame oil group: The participants rubbed 1cc of sesame oil 2 times daily on their abdomen and massaged it for 5 minutes during 20 weeks from 16 to 36 weeks of gestation. The almond group: The participants rubbed 1cc of sweet almond oil 2 times daily on their abdomen and massaged it for 5 minutes during 20 weeks from 16 to 36 weeks of gestation. The control group: The participants in this group did not use any substance or drug to prevent of striae gravidarum from 16 to 36 weeks of gestation.

##### Main outcome variables

The incidence of striae gravidarum

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20091111002699N6**

Registration date: **2018-07-06, 1397/04/15**

Registration timing: **retrospective**

Last update: **2018-07-06, 1397/04/15**

Update count: **0**

##### Registration date

2018-07-06, 1397/04/15

##### Registrant information

##### Name

Farzaneh Saberi

##### Name of organization / entity

Kashan University Of Medical Siences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 5554 0021

##### Email address

saberi\_f@kaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2014-07-06, 1393/04/15

##### Expected recruitment end date

2017-09-21, 1396/06/30

##### Actual recruitment start date

2014-07-11, 1393/04/20

##### Actual recruitment end date

2018-02-19, 1396/11/30

##### Trial completion date

empty

## Scientific title

Comparison of the effect of sesame oil and almond oil on preventing the striae gravidarum

## Public title

Effect of sesame oil and almond oil on the striae gravidarum

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

The current gestational age is 16 weeks no history of abortion at gestational age 16 weeks or more singleton pregnancy being Iranian being nulliparous

### Exclusion criteria:

use of other substances for the prevention or treatment of striae presence of striae having Cushing's disease having diabetes use of alcohol BMI >30

## Age

From **15 years** old to **45 years** old

## Gender

Female

## Phase

3

## Groups that have been masked

- Outcome assessor

## Sample size

Target sample size: **150**

Actual sample size reached: **134**

## Randomization (investigator's opinion)

Randomized

## Randomization description

simple randomization using random number table

## Blinding (investigator's opinion)

Single blinded

## Blinding description

Almond oil and sesame oil were prepared in completely similar glasses, and the research associate were unaware of the oil type.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

##### Street address

5th of Qotb -e Ravandi Blvd., Kashan, IRAN

##### City

Kashan

## Province

Isfahan

## Postal code

8715988141

## Approval date

2014-06-26, 1393/04/05

## Ethics committee reference number

1507/1/5/29/پ

## Health conditions studied

### 1

#### Description of health condition studied

striae gravidarum

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Incidence of striae gravidarum

#### Timepoint

Weeks 16, 20, 24, 28, 32 and 36 gestation

#### Method of measurement

Davey's score

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

First intervention group, Almond oil user group: The participants in this group rubbed 1cc of sesame produced by Barij Essence Pharmaceutical Co. oil 2 times daily on their abdomen and massaged it for 5 minutes during 20 weeks from 16 to 36 weeks of gestation.

#### Category

Prevention

### 2

#### Description

Intervention group: Sesame oil user group Group: The participants in this group rubbed 1cc of sweet almond oil produced by Barij Essence Pharmaceutical Co. 2 times daily on their abdomen and massaged it for 5 minutes during 20 weeks from 16 to 36 weeks of gestation.

#### Category

Prevention

### 3

#### Description

Control group: The participants in this group did not use any substance or drug to prevent of striae gravidarum

from 16 to 36 weeks of gestation.

**Category**

Prevention

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Health Centers

**Full name of responsible person**

Farzaneh Saberi

**Street address**

5th of Qotb -e Ravandi Blvd, Faculty of Nursing & Midwifery, Kashan, IRAN

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**Postal code**

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**Email**

saberi\_f@kaums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Gholam Ali Hamidi (Ph.D)

**Street address**

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hamidi\_gh@kaums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Kashan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Academic

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Farzaneh Saberi

**Position**

Associate

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

**Street address**

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**Person responsible for scientific inquiries**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Farzaneh Saberi

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**Latest degree**

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**Email**

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Not applicable

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

Not applicable

### Title and more details about the data/document

Total data is Sharable after unidentifiable people.

### When the data will become available and for how long

Start the access period: 6 months after printing the results.

### To whom data/document is available

Researchers working in college or industry-based companies can take data from this study.

### Under which criteria data/document could be used

Researchers working in college or industry-based companies can use the results after getting permission from the authors of the study.

### From where data/document is obtainable

5th of Qotb -e Ravandi Blvd., Farzaneh Saberi, Faculty of Nursing & Midwifery, Kashan, IRAN P.O.Box: 8715981151  
E-mail: saberi\_f@kaums.ac.ir

### What processes are involved for a request to access data/document

Two weeks after receiving a request

### Comments