

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### The Effect of sesame oil , sweet almond oil and combination of the both of sesame oil \_ sweet almond oil on prevention of striae gravidarum in nulliparous women:A randomized controlled clinical trial

#### Protocol summary

##### Summary

**Objectives:** This study aims to determine the Effect of sesame oil, sweet almond oil and combination of the both of sesame oil \_ sweet almond oil on prevention of striae gravidarum in nulliparous women. **Design:** Triple blind Randomized Controlled Trial. **Setting and conduct:** This study will be conducted in arak health centers. **Eligible women** will be selected with convenience sampling and will be randomly assigned into 4 groups of 50 subjects with block sizes of 4 and 8. A person from research team not involved in the recruitment and assigning participants will generate allocation sequence using a computerized program. Opaque sealed sequentially numbered envelopes will be used for allocation concealment. **Participants:** 200 nulliparous women aged 18 to 35 years with gestational age of 16 to 20 weeks who have not any striae on the abdomen, thighs, arms and breasts and don't using any other herbal or chemical drugs on their abdomen. **Interventions:** After completing the basic information, one intervention group will receive sesame oil (1cc, twice a day) and second intervention group will receive sweet almond oil (1 cc, twice a day). Third group will receive the combination of sesame oil and sweet almond oil (1 cc, twice a day). The control group will receive placebo. **Main outcome measures:** Incidence and severity of striae will be evaluated by the Davey method and incidence and severity of irritation will be evaluated by Kamini method at the end of the intervention. **Secondary outcomes** include the comparison of side events of the oils among the intervention groups that will be evaluated by the checklist.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201208048170N3**

Registration date: **2013-09-22, 1392/06/31**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2013-09-22, 1392/06/31

##### Registrant information

###### Name

Jamileh Malakouti

###### Name of organization / entity

Nursing Faculty

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1477 2699

###### Email address

malakoutij@tbzmed.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

##### Expected recruitment start date

2013-09-23, 1392/07/01

##### Expected recruitment end date

2013-12-22, 1392/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of sesame oil , sweet almond oil and combination of the both of sesame oil \_ sweet almond oil on prevention of striae gravidarum in nulliparous women:A randomized controlled clinical trial

#### Public title

The Effect of sesame oil , sweet almond oil and combination of the both of sesame oil \_ sweet almond oil on prevention of striae gravidarum in nulliparous women:A randomized controlled clinical trial

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

1.Pregnant women with gestational age of 25-30 weeks aged 18 to 35 years old; pregnant women Age group between 18-35,2. Being nulliparous, 3.Having a single aliving fetous, 4. Gestational age 16-20 weeks (according last menstruation period or sonography ),5.Body mass index between 19.8-25, 6.Not having known coronic diseases such as adrenal disorders and diabetes (according woman telling ), 6. being literate, 7.Not using an other herbal or chemical drugs during pregnancy, 8. Not having any estriae on the abdomen ,arms,thighs and breasts 9.Being able to use the oils twice aday 10.Not going on any special diet. exclusion criteria :1.Having known skin diseases;2.polyhydraminious pregnancy;3.having allergy history to studied drugs;4.Having past surgical history on the abdomen;5.Having any malegnancy on the abdomen

#### Age

From **18 years** old to **35 years** old

#### Gender

Female

#### Phase

2-3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **200**

#### 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

Ethics committee of Tabriz University of Medical

Sciences

#### Street address

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, East Azerbaijan

#### City

Tabriz

#### Postal code

00984113357311

#### Approval date

2013-08-11, 1392/05/20

#### Ethics committee reference number

9290

### Health conditions studied

#### 1

##### Description of health condition studied

Striae gravidarum

##### ICD-10 code

026.9

##### ICD-10 code description

Pregnancy, childbirth and the puerperium

### Primary outcomes

#### 1

##### Description

The incidence of estriae

##### Timepoint

At the end of the intervention

##### Method of measurement

The vising by educated midwives

#### 2

##### Description

Severity of the estriae

##### Timepoint

At the end of the intervention

##### Method of measurement

Davey method

#### 3

##### Description

The incidence of the irritation

##### Timepoint

At the end of the intervention

##### Method of measurement

Kamini method

#### 4

##### Description

The severity of the irritation

##### Timepoint

At the end of the intervention

##### Method of measurement

## Secondary outcomes

### 1

#### Description

The comparison of the side events of the oils among intervention groups

#### Timepoint

At the end of the intervention

#### Method of measurement

The checklist

## Intervention groups

### 1

#### Description

The first intervention group will received 1 cc sesame oil twice a day during 20 weeks

#### Category

Prevention

### 2

#### Description

The second intervention group will received 1 cc sweet almond oil ,twice a day during 20 weeks

#### Category

Prevention

### 3

#### Description

The third intervention group will received 1 cc the combination of sweet almond oil and sesame oil ,twice a day during 20 weeks

#### Category

Prevention

### 4

#### Description

The control group will received 1 cc placebo oil ,twice a day during 20 weeks.The placebo oil incudes distilled water and lubricant jel

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Arak health centers

##### Full name of responsible person

Kamrani Atefeh

##### Street address

Nursing & Midwifery Faculty, South Shariati Street

##### City

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

##### Full name of responsible person

Shakouri Seyyed Kazem

##### Street address

Research department, third floor, central construction number 2, Tabriz medical science university, Golgasht Street, Azadi Avenue

##### City

Tabriz

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Vice chancellor for research, Tabriz 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

Faculty of Nursing & Midwifery, Tabriz University of Medical Sciences

##### Full name of responsible person

Kamrani Atefeh

##### Position

MSc student in Midwifery

##### Other areas of specialty/work

##### Street address

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+98 86 3224 3459

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atykamrani@yahoo.com

##### Web page address

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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## Person responsible for updating data

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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*