Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 envelops 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

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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 mensturation 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

Kamini method

Secondary outcomes

1

Description
The comparision 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 recieved 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
Tabriz

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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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Malakouti Jamileh

Position
MSc in Midwifery

Other areas of specialty/work

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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