

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of rose damascene oil, sesame oil and placebo on the prevention of striae gravidarum in nulliparous women: A randomized controlled clinical trial

Protocol summary

Study aim

Comparison of incidence and severity of striae and severity of itching in the intervention (sesame oil, rose damascene oil) and placebo groups

Design

A randomized controlled triple blinded clinical trial with three parallel arm design on 150 pregnant women

Settings and conduct

Research setting is health centers of Arak city. Patients will be randomly assigned to groups based on the block random allocation method. In the present study, participants, researchers, clinical caregivers, and analyzer will not be aware of the contents of the tubes; so the study will be triple blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Gestational age of 16-20 weeks; Nulliparity; being at the age of 18-35 years old; BMI between 18.5-25 kg/ m2. Non-inclusion criteria: Previous scar on abdomen; Allergy to rose oil or sesame oil; use of other herbal or chemical medicines on affected area.

Intervention groups

Intervention group 1: sesame oil 10%, Intervention group 2: rose damascene oil 10%, Intervention group 3: placebo control. Placebo will contain base cream of stearic acid identical with main creams. Topical creams will be used twice daily from 16th to 20th week of pregnancy for 20 weeks on the abdominal skin without rubbing.

Main outcome variables

Incidence of striae; Severity of striae; Incidence of itching; Severity of itching resulted from striae

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131009014957N9**

Registration date: **2020-03-14, 1398/12/24**

Registration timing: **prospective**

Last update: **2020-03-14, 1398/12/24**

Update count: **0**

Registration date

2020-03-14, 1398/12/24

Registrant information

Name

Azizeh Farshbaf-khalili

Name of organization / entity

Tabriz university of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1333 9151

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-14, 1399/03/25

Expected recruitment end date

2021-06-15, 1400/03/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of rose damascene oil, sesame oil and placebo on the prevention of striae gravidarum in nulliparous

women: A randomized controlled clinical trial

Public title
The Effect of rose damascene oil and sesame oil on the prevention of striae gravidarum

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Gestational age of 16-20 weeks Having a single live fetus
 Nulliparity Being at the age of 18-35 years Body mass index of 18.5-25 kg /m2 Being literate (at least writing and reading skills)
Exclusion criteria:
 The use of other herbal or chemical drugs on the affected area Sensitivity to rose oil and sesame oil and not being able to use the drug twice daily Taking corticosteroids previous striae Surgical scar on the abdomen Having chronic diseases Having adrenal glands diseases Presence of skin disease

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

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description
Using a computerized random number table, taking into account blocks of size 6 and 9, with a 1: 1: 1 allocation ratio

Blinding (investigator's opinion)
Triple blinded

Blinding description
Since the drugs (medications) will be prepared in similar tubes; participant, researcher, clinical caregiver and intervention analyst will not be aware of the content of the tubes.

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
 Nutrition Research Center, Tabriz University of Medical Sciences; Attar Neishabouri avenue, Golgasht
City
 Tabriz
Province
 East Azarbaijan
Postal code
 5166614711
Approval date
 2020-02-03, 1398/11/14
Ethics committee reference number
 IR.TBZMED.REC.1398.1185

Health conditions studied

1

Description of health condition studied
Pregnancy striae

ICD-10 code
L99

ICD-10 code description
Other disorders of skin and subcutaneous tissue in diseases classified elsewhere

Primary outcomes

1

Description
Incidence rate of gestational striae

Timepoint
Evaluation of incidence in 35-37 weeks of gestation

Method of measurement
Davey method

2

Description
Incidence rate of itching

Timepoint
The incidence of pruritus in 35-37 weeks of gestation

Method of measurement
Kamini method

3

Description
Severity of gestational striae

Timepoint
Evaluation of severity of striae in 35-37 weeks of gestation

Method of measurement
Davey method

4

Description

Severity of itching

Timepoint

Evaluation of severity of pruritus in 35-37 weeks of gestation

Method of measurement

Kamini method

Secondary outcomes

1

Description

Satisfaction of medication use

Timepoint

35-38 weeks of gestation

Method of measurement

Satisfaction Questionnaire

2

Description

Side effects

Timepoint

35-38 weeks of gestation

Method of measurement

Side effects Questionnaire

Intervention groups

1

Description

Intervention group 1: Rose damascene oil. The 10% rose damascene oil at the base of the cream will be produced by a pharmacognosist at the Biotechnology Research Center and it will be supplied in the numbered, identical size and color tubes . The drug will be applied topically twice daily to the abdomen without rubbing, from 16th to 20th week of gestation for 20 weeks.

Category

Prevention

2

Description

Intervention group 2: Sesame Oil. The 10% sesame oil at the base of the cream will be produced by a pharmacognosist at the Biotechnology Research Center and it will be supplied in the numbered, identical size and color tubes . The drug will be applied topically twice daily to the abdomen without rubbing, from 16th to 20th week of gestation for 20 weeks.

Category

Prevention

3

Description

Control group: placebo. Base cream (stearic acid) as placebo will be produced by a pharmacognosist at the

Biotechnology Research Center and it will be supplied in the numbered, identical size and color tubes . The drug will be applied topically twice daily to the abdomen without rubbing, from 16th to 20th week of gestation for 20 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Arak Health Centers

Full name of responsible person

Fatemeh Mirzaei

Street address

Shahid Shiroudi Street, Alam al-Hadi Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Samiei

Street address

Headquarters of the University, Golgasht Street, Azadi Street

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Web page address

<https://researchvice.tbzmed.ac.ir/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Medical Sciences, Attar Neyshabouri avenue,
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Web page address**Person responsible for general inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Azizeh Farshbaf-khalili

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Others

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Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Others

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Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Others

Street address

Nutrition Research Center, Tabriz University of

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

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available
Title and more details about the data/document
Part of the outcome data is published
When the data will become available and for how long
6 months after printing the results
To whom data/document is available
Researchers at institutions have access to data
Under which criteria data/document could be used

To help with scientific progress in the field of research
From where data/document is obtainable
farshbafa@tbzmed.ac.ir
What processes are involved for a request to access data/document
Scientific approval of applicant by Tabriz University of Medical Sciences
Comments