Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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)

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+98 41 1333 9151

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farshbafa@tbzmed.ac.ir

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
City
Arak
Province
Markazi
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3819693345
Phone
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fatememirzayi1368@gmail.com
Web page address
https://arakmu.ac.ir/arakdh/fa

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
City
Tabriz
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East Azarbaijan
Postal code
5166616471
Phone
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Fax
+98 41 3334 4280
Email
Samiei.moh@gmail.com
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

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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Person responsible for updating data

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Position
Assistant Professor
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Other areas of specialty/work
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Web page address

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