

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Comparison the effect of Aloe Vera gel and Sweet Almond oil on Striae Gravidarum in nulliparous women

Protocol summary

Summary

In this study we investigate and compare the effect of Aloe Vera gel and sweet almond oil, which had been traditionally used, on striae gravidarum. In this double blind clinical trial 160 nulliparous women enroll and randomly divide into 3 intervention groups and 1 control group. The first, the second and the third groups respectively will be given 700g Aloe Vera cream, sweet almond oil cream and base cream to use topically on the abdominal skin. Inclusion criteria: 20-35-years-old nulliparous women with normal body mass index (18.5-26); informed consent for participation in the study; using no topical medication for the treatment or prevention of striae before entering the study; and having no skin diseases. Exclusion criteria: twin pregnancy; Polyhydramnios; preterm labor; the subject's unwillingness to participate in the study; early termination of the cream; below 2 kg or above 4 kg infant birth weight; and using creams other than one prescribed for the study. Then, within six stages, they will be examined in terms of the study's variables (itching and erythema and spread and diameter of striae).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016110827998N4**

Registration date: **2016-12-11, 1395/09/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-12-11, 1395/09/21

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Shahrekord University of Medical Sciences

Expected recruitment start date

2012-06-30, 1391/04/10

Expected recruitment end date

2013-06-30, 1392/04/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of Aloe Vera gel and Sweet Almond oil on Striae Gravidarum in nulliparous women

Public title

Comparison the effect of Aloe Vera gel and Sweet Almond oil on Striae Gravidarum in nulliparous women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 20 to 35 years old nulliparous women with normal body mass index (18.5 to 26); informed consent for participation in the study; using no topical medication for the treatment or prevention of striae

before entering the study; and having no skin diseases. Exclusion criteria: twin pregnancy; Polyhydramnios; preterm labor; the subject's unwillingness to participate in the study; early termination of the cream; below 2 kg or above 4 kg infant birth weight; and using creams other than one prescribed for the study.

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice Chancellor for research of Shahrekord University of Medical Sciences

Street address

Building number 2, university complex, Edarat avenue, Shahrekord

City

Shahrekord

Postal code

Approval date

2011-08-07, 1390/05/16

Ethics committee reference number

12-5-90

Health conditions studied

1

Description of health condition studied

steria gravidarum

ICD-10 code

026.8

ICD-10 code description

Other specified pregnancy-related conditions

Primary outcomes

1

Description

the number of abdominal areas affected by striae ,

Timepoint

during a six months period and in monthly

Method of measurement

the number of abdominal areas affected by striae (abdomen division into four zones) was measured by the examiner based on counting the number of areas

2

Description

number of striae

Timepoint

during a six months period and in monthly

Method of measurement

the number of striae was measured based on the observer's observations

Secondary outcomes

1

Description

itching

Timepoint

during a six months period and in monthly

Method of measurement

itching (qualitative measure: low, medium, high) based on the subject's expression

2

Description

Striae diameter ,

Timepoint

during a six months period and in monthly

Method of measurement

by calipers

3

Description

erythema

Timepoint

during a six months period and in monthly

Method of measurement

qualitative measure: low, medium, high) by the observer's observation

Intervention groups

1

Description

Intervention group 1 : Will be given 700 g combination of aloe Vera (extracted from aloe Vera leaves) in a cream base and in a 1 to 1 ratio to rub 2g every 12 hours gently

and without massage on the abdominal skin from the 16th week of pregnancy until the delivery day. The amount of cream will be calculated based on the Finger Tip Unit (FTU) (26).

Category

Treatment - Drugs

2

Description

Intervention group 2 : Each subject will be given 700 g combination of sweet almond oil in a cream base to rub 2g every 12 hours gently and without massage on all abdominal area from the 16th week of pregnancy until the delivery day. The amount of cream will be calculated based on the Finger Tip Unit (FTU) (26).

Category

Treatment - Drugs

3

Description

Control group 1 :They will only be given 700g base cream to rub 2g every 12 hours gently and without massage on all abdominal area from the 16th week of pregnancy until the delivery day.

Category

Placebo

4

Description

Control group 2 : They will be received no medication to treat or prevent striae.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Share-kord Imam Ali Gynecological clinic

Full name of responsible person

Dr Shadi Memarian

Street address

Imam Ali Gynecological clinic, Parastar avenue, Shahre-Kord

City

Shahrekord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of ShahreKord University of Medical Sciences

Full name of responsible person

Dr Seyed Kamal Solati

Street address

Bilding number 2, University Setad, Ayatolah Kashani avenue, ShahreKord

City

ShahreKord

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 of ShahreKord 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

Shehrekord University of Medical Sciences

Full name of responsible person

Maryam Hajhashemy

Position

Assistant Professor

Other areas of specialty/work

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bridge, esfahan**City****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*