

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of topically-applied combined herbal cream on prevention of Striae gravidarum in nulligravida women

Protocol summary

Study aim

Determination of the Effect of Consumption of Calendula, Chamomile, Geranium, Cocoa and Soybean bean on Streams of Pregnancy in Pregnant Women

Design

Randomized controlled trial phase 3, the Parallel-group with the triple blinded. 140 pregnant nulliparous women. Simple randomization.

Settings and conduct

The research site will be Mashhad health centers. The study is triple blind and parallel controlled clinical trials. In this study, the participants, the researchers and the person who performs the analysis of results will be blinded.

Participants/Inclusion and exclusion criteria

Pregnant nullipara women, Gestational Age range 14-16 week, Age range 20-35 year, BMI range 18.5-25 Kg/m², No smoking, Not having any chronic diseases (Cardiovascular, Hypertension, diabetes, ...)

Intervention groups

Intervention group: use of topically-applied herbal cream twice a day in four regions of the abdomen Control group: Use of placebo cream twice a day in four regions of the abdomen

Main outcome variables

The number, severity, and size of gravidarum striae

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180926041143N1**
Registration date: **2019-01-02, 1397/10/12**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-02, 1397/10/12**

Update count: **0**

Registration date

2019-01-02, 1397/10/12

Registrant information

Name

Somayeh Alirezaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3501 2276

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-06, 1397/07/14

Expected recruitment end date

2019-04-03, 1398/01/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of topically-applied combined herbal cream on prevention of Striae gravidarum in nulligravida women

Public title

The effect of topically-applied combined herbal cream on Striae gravidarum in nulligravida women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant nullipara women Gestational Age range 14-16 week Age range 20-35 year BMI range 18.5-25 Kg/m² No

smoking Not having any chronic diseases
(Cardiovascular, Hypertension, diabetes, ...)

Exclusion criteria:

Age

From **20 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: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be based on simple randomization. The method used to randomize will be a random number table. To hide random assignments, numbered drug containers with random number sequences will be used.

Blinding (investigator's opinion)

Triple blinded

Blinding description

For the primary blindness of the study, since the possibility of sampling is different between the two groups, pregnant women have no knowledge of the contents of the cans in the other group. The second stage of blinding is that the researcher's assistance in the field of training and delivery of cans does not have the information on the type of the groups and the contents of the cans, and only records the cans in the sample form when the code is delivered. The next steps are to get the worm by the manufacturer to fit the group that belongs to him. The final stage of blindness is in relation to the individual who will analyze the results. She is also unaware of the groups and intervention. The research team leader will only decode the codes after analyzing the results.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Mashhad University of Medical Sciences

Street address

Mashhad University of Medical Sciences, Num 18,
Daneshgah Ave, Mashhad Town

City

Mashhad

Province

Razavi Khorasan

Postal code

38412081

Approval date

2018-10-03, 1397/07/11

Ethics committee reference number

IR.MUMS.NURSE.REC.1397.040

Health conditions studied

1

Description of health condition studied

Steriae Gravidarum

ICD-10 code

ICD-10 code description

ster

Primary outcomes

1

Description

The number, Severity and Size of Steriae Geravidarum based on Atwal Scoring

Timepoint

Evaluation of Steriae Gravidarum at 27-30 and 38-40 of Gestational Age

Method of measurement

The numerical scoring system of Atwal

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Herbal cream consisting of Calendula, Chamomile, Geranium, Cocoa and soybean seeds on pregnancy stretch from 14-16 weeks of gestation in primiparous women, twice daily by 0.3 grams or a half teaspoon in all four areas From the body, including 1. Separate the umbilicus to the symphysis pubis 2. Immediately above the umbilical in the transverse direction, 3. The right side in the longitudinal direction, 4. The left side, in the longitudinal direction, and massage gently, until the end of pregnancy. This herbal cream is made by Tus Amithis Ariaia company, under the supervision of the Center for the Growth of the Buali Institute in Mashhad.

Category

Prevention

2

Description

Control group: Placebo cream consisting of Calendula, Chamomile, Geranium, Cocoa and soybean seeds on pregnancy stretch from 14-16 weeks of gestation in primiparous women, twice daily by 0.3 grams or a half teaspoon in all four areas From the body, including 1. Separate the umbilicus to the symphysis pubis 2. Immediately above the umbilical in the transverse direction, 3. The right side in the longitudinal direction, 4. The left side, in the longitudinal direction, and massage gently, until the end of pregnancy. This herbal cream is made by Tus Amithis Ariaia company, under the supervision of the Center for the Growth of the Buali Institute in Mashhad.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Health center 1 mashhad

Full name of responsible person

Somayeh Alirezaei

Street address

Between 66th & 68th Vakil Abad, Vakil Abad Ave, Mashhad Town

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2

Recruitment center

Name of recruitment center

Health center 3 Mashhad

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

50

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

Mashhad University of Medical Sciences

Full name of responsible person

Somayeh Alirezaei

Position

PhD Student of Reproductive Health

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

So far, there is no definite program and protocol in Mashhad University of medical sciences.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available