Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of vitamin D and vitamin C cream and their composition on pregnancy striae in first pregnant women

Protocol summary

Study aim

Comparison of the effect of vitamin D ,vitamin C creams and their combined on pregnancy striae in first pregnant women

Design

Clinical trial with control group, with parallel groups, three-way blind, randomized,phase3 on 120patients.For randomization,the seal envelope site is used by specifying the number of 8and16 random blocks

Settings and conduct

The study population was first pregnant women aged 20-18 weeks who referred to Shahid Akbarabadi Hospital. Thus, follow-up will be done during pregnancy for 4 months. Samples will be randomly assigned to one of the groups: vitamin C+D cream or vitamin D or vitamin C or placebo group. Before starting the study, a hypothetical list of 120 items was prepared through the random block method by sealing the envelope site by specifying the number of blocks of 8 and 16, for participants in 4 groups of 30, A, B, C, and D will be created. Numbered, matte, and sealed envelopes will be used to hide the allocation and protect the blind. In this way, the participants will be blinded. One group of cream with code A will be given to another group with cream with code B, another group with cream with code C, and another group with cream with code D.Since this study is a three-blind clinical trial, for the blinding of the researcher and analyst, the worms will be identified with codes A, B, C, D and the type of worms will not be specified.

Participants/Inclusion and exclusion criteria

Healthy first pregnant women in the age group of 20-40 years,18-20 weeks and body mass index 18.5-25;Have a minimum literacy;Known systemic or underlying disease;Multiple pregnancy;History of pre-striae skin diseases;History of allergies to vitamins D&C;Maternal polyhydramnios;Diagnosis of macrosomia

Intervention groups

Intervention groups Consumer of vitamin D Consumer of vitamin C Consumer of vitamin D+C Placebo group Consumer of base cream

Main outcome variables

Pregnancy striae

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220509054799N1**
Registration date: **2022-06-06, 1401/03/16**
Registration timing: **registered_while_recruiting**

Last update: **2022-06-06, 1401/03/16**
Update count: **0**

Registration date

2022-06-06, 1401/03/16

Registrant information

Name

Hadis Taheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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taheri.h@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-09-23, 1401/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of vitamin D and vitamin C cream and their composition on pregnancy striae in first pregnant women

Public title

Comparison of the effect of vitamin D and vitamin C cream and their composition on pregnancy striae in first pregnant women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Primigravid healthy pregnant women The age group of 20-40 years, 18-20 weeks pregnancy Body mass index 18.5-25 Have a minimum literacy

Exclusion criteria:

Known systemic or underlying disease (such as gestational diabetes, preeclampsia, adrenal insufficiency, and Cushing's disease) Multiple pregnancies History of pre-striae skin diseases History of allergies to vitamin D and C. Maternal polyhydramnios Diagnosis of macrosomic embryos

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Before starting the study, a hypothetical list of 120 pieces was prepared and through the random block method by seal envelope site by specifying the number of blocks of 8 and 16, for participants in four groups of 30 worms A and worm B And worm C and worm D will be created. Numbered, matte and sealed envelopes will be used to hide the allocation and protect the blind. The envelopes will be opened in the order in which the participants enter the study. Eventually, 30 people will enter each group. One group will be given cream with code A, another group with cream with code B, another group with cream with code C and another group with cream with code D. These creams will be prepared by the order of the researcher and by a pharmaceutical consultant in the School of Traditional Medicine of Iran. Since this study is a three-blind clinical trial, the worms will be identified by codes A, B, C and D, and the type of worms will not be identified.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Numbered, matte and sealed envelopes will be used to hide the allocation and protect the blind. The envelopes will be opened in the order in which the participants enter the study. Eventually, 30 people will enter each group. One group of worms with code A will be given another group of worms with code B, another group with worms with code C and another group with worms with code D, thus blinding the participants. These creams will be prepared by the order of the researcher and by a pharmaceutical consultant in the School of Traditional Medicine of Iran. Since this study is a three-blind clinical trial, in order to keep the researcher and analyzer of the worms blind, the codes A, B, C and D will be specified and the type of worms will not be specified.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

Street address

Hemmat Highway between Chamran and Sheikh Fazlollah Iran University of Medical Sciences Headquarters Fifth Floor

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2022-06-01, 1401/03/11

Ethics committee reference number

IR.IUMS.REC.1401.215

Health conditions studied

1

Description of health condition studied

Pregnancy striae

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Striae are skin changes that occur in situations where the skin is under the physical pull of sudden growth during adolescence, pregnancy, or in conditions such as Cushing's syndrome, in which severe hormonal changes occur in the body. In mid-pregnancy, reddish, slightly sunken streaks usually form on the skin of the abdomen and sometimes on the skin above the breasts and thighs. These are called stria gravidarum or stretch marks. These lines lose their pigmentation some time after delivery, turn oyster white, and eventually remain atrophic, slightly wrinkled, and sunken over time.

Timepoint

Before, 4, 8, 12 and 16 weeks after the start of the intervention

Method of measurement

In this study, the practical definition is in accordance with the above theoretical definition and the Atwal scale is used to measure this variable. This scale is used to classify women based on the severity of striae. Based on this system, the abdomen, breast, thighs and buttocks are examined for the severity of erythema and the number of stretch marks. The maximum score in each area is 6. The total score is 0-3 without striae or without significant striae, the total score is 4-9 mild striae, the total score is 10-15 moderate striae and the total score is more than 16 is severe striae.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Consumer of vitamin D - Participants receive topical vitamin D 5000 units per 100 grams of uranda base cream (containing alcohol, glycerin, triethanolamine, mono-stearic acid, white Vaseline and distilled water) for 4 months. This cream will be prepared by the order of the researcher and by a pharmaceutical consultant in the School of Traditional Medicine of Iran. How to use it is that this cream for 4 months daily, twice a day every 12 hours using the finger, topically and gently and without massaging the skin of the abdomen, thighs, breasts and buttocks to cover Apply all those areas with a thin layer of cream and people are asked not to wash it after use until it is absorbed.

Category

Prevention

2

Description

Intervention group: Consumer of vitamin C - Participants receive 3% topical vitamin C in 100 g of uranda base cream (containing alcohol, glycerin, triethanolamine, mono-stearic acid, white Vaseline and distilled water) for 4 months. This cream will be prepared by the order of the researcher and by a pharmaceutical consultant in the School of Traditional Medicine of Iran. How to use it is that this cream for 4 months daily, twice a day every 12 hours using the finger, topically and gently and without massaging the skin of the abdomen, thighs, breasts and buttocks to cover Apply all those areas with a thin layer of cream and people are asked not to wash it after use until it is absorbed.

Category

Prevention

3

Description

Intervention group: Consumer of Vitamin C + D - Participants of topical vitamin D 5000 units in 100 g of Orande base cream (containing alcohol, glycerin, triethanolamine, monostaric acid, white Vaseline and distilled water) with topical vitamin C 3%, Receive for 4 months. This cream will be prepared by the order of the researcher and by a pharmaceutical consultant in the School of Traditional Medicine of Iran. How to use it is that this cream for 4 months daily, twice a day every 12 hours using the finger, topically and gently and without massaging the skin of the abdomen, thighs, breasts and buttocks to cover Apply all those areas with a thin layer of cream and people are asked not to wash it after use until it is absorbed.

Category

Prevention

4

Description

Control group: Base Cream Consumer - Participants receive Eurend Base Cream containing alcohol, glycerin, triethanolamine, mono-stearic acid, white Vaseline and distilled water for 4 months. This cream will be prepared by the order of the researcher and by a pharmaceutical consultant in the School of Traditional Medicine of Iran. How to use it is that this cream for 4 months, daily, twice a day for 12 hours using a finger, topically and gently and without massaging the skin of the abdomen, thighs, breasts and buttocks to the cover Apply all those areas with a thin layer of cream and people are asked not to wash it after use until it is absorbed.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Akbarabadi hospital

Full name of responsible person

Ms Salamatmanesh

Street address

Molavi St, not reached the Molavi Crossroads

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Web page address
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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
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Dr. Masoumeh Kheirkhah
Position
Assistant Professor of Midwifery
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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Street address
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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
There is no more information.
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
Yes - There is 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
Title and more details about the data/document
Failure to disclose information in order to maintain confidentiality
When the data will become available and for how long
Failure to disclose information in order to maintain confidentiality
To whom data/document is available
Failure to disclose information in order to maintain confidentiality
Under which criteria data/document could be used
Failure to disclose information in order to maintain confidentiality
From where data/document is obtainable
Failure to disclose information in order to maintain confidentiality
What processes are involved for a request to access data/document
Failure to disclose information in order to maintain confidentiality
Comments
In the clinical study report section, the report will be submitted to the research system according to the guidance of the university.