# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

21 Jul 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**
+98 21 6692 2918

**Email address**
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

**City**

Tehran

**Province**
Tehran
**Postal code**
1168743514
**Phone**
+98 21 5560 6034
**Email**
akbarabadihosp@yahoo.com
**Web page address**
https://crta.iums.ac.ir/

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Iran University of Medical Sciences
**Full name of responsible person**
Dr. Hossein Keivani
**Street address**
Hemmat Highway between Chamran and Sheikh Fazlollah Iran University of Medical Sciences Headquarters Fifth Floor
**City**
Tehran
**Province**
Tehran
**Postal code**
۱۴۴۹۶۱۴۵۳۵
**Phone**
+98 21 8670 2503
**Fax**
+98 21 8862 2703
**Email**
research@iums.ac.ir
**Web page address**
https://res.iums.ac.ir/
**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**
Midwifery
**Street address**
Vali Asr Street, above Vanak Square, Rashid Yasemi Street Iranian School of Nursing and Midwifery
**City**
Tehran
**Province**
Tehran
**Postal code**
۱۹۹۶۷۱۳۸۸۳
**Phone**
+98 21 4365 1000
**Fax**
+98 21 8820 1978
**Email**
kheirkhah.m@iums.ac.ir
**Web page address**
https://fnm.iums.ac.ir/

## Person responsible for scientific 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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**Street address**
Vali Asr Street, above Vanak Square, Rashid Yasemi Street Iranian School of Nursing and Midwifery
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۱۹۹۶۷۱۳۸۸۳
**Phone**
+98 21 4365 1000
**Fax**
+98 21 8820 1978
**Email**
kheirkhah.m@iums.ac.ir
**Web page address**
https://fnm.iums.ac.ir/

## Person responsible for updating data

**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**
Midwifery

**Street address**
Vali Asr Street, above Vanak Square, Rashid Yasemi Street Iranian School of Nursing and Midwifery

**City**
Tehran

**Province**
Tehran

**Postal code**
۱۹۹۶۷۱۳۸۸۳

**Phone**
+98 21 4365 1000

**Fax**
+98 21 8820 1978

**Email**
kheirkhah.m@iums.ac.ir

**Web page address**
https://fnm.iums.ac.ir/

## 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.