Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

A study on the effect of ointment of pistacia atlantica oil on the prevention of stretch marks in primigravid wemon

Protocol summary

Study aim
Determining the effect of ointment of pistacia atlantica oil on the prevention of stretch marks in primigravid wemon

Design
A three-blind randomized controlled clinical trial will be conducted on 140 first-time pregnant women who are eligible to participate in the study and refer to the health centers of Zahedan city, who will be selected as available, then the research units will be randomly assigned to two intervention groups. (Ointment) and placebo will be placed. The sequence of random allocation of people to the studied groups will be done by Allocation Concealment method.

Settings and conduct
This study will be conducted in the field of herbal medicine with the aim of determining the effect of Beneh ointment on the prevention of pregnancy stretch marks in first-time pregnant women. Each of the intervention and control groups has 70 samples.

Participants/Inclusion and exclusion criteria
1) Informed consent to participate in the study 2) Age between 20 and 35 years 3) Being pregnant for the first time 4) Pregnancy age between 24 and 26 weeks 4) Singleton pregnancy 6) Not using corticosteroids and any type of topical or systemic corticosteroids 7) Not using any kind of cream or oil in the abdominal area 8). The mother does not suffer from obstetric problems such as: hydramnios, provia 9). Body mass index should be between 18.50 and 30. 10). Mother's absence of Cushing's disease11). The absence of the mother from Marfan's disease 12). The absence of the mother from anorexia nervosa 13). The absence of the mother from chronic liver disease 14). The absence of any type of lesion or wound at the intervention site 15). Not having diabetes 16). Absence of allergy to Beneh ointment or no history of allergy to Beneh fruit 17). Mother's absence of previous stretch marks in the abdominal area.

Intervention groups
pistacia atlantica oil

Main outcome variables
Stretch, Erythema,Itching

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230720058860N1**
Registration date: **2023-11-27, 1402/09/06**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-27, 1402/09/06**
Update count: **0**

Registration date
2023-11-27, 1402/09/06

Registrant information

Name
Mansureh Tork Hesari tavakoli

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 915 044 0914

Email address
torkhesarim4001@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-07, 1402/07/15

Expected recruitment end date
2024-03-05, 1402/12/15

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A study on the effect of ointment of pistacia atlantica oil on the prevention of stretch marks in primigravid wemon

Public title

A study on the effect of ointment of pistacia atlantica oil on the prevention of stretch marks in primigravid wemon

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Informed consent to participate in the study Age between 20 and 35 years Being pregnant for the first time Pregnancy age between 22 and 26 weeks Singleton pregnancy Not using corticosteroids and any type of topical or systemic corticosteroids Not using any kind of cream or oil in the abdominal area Not suffering from hydramnios Body mass index at the beginning of pregnancy or in the last trimester of the first trimester should be between 18.50 and 30 Mother's absence of Cushing's disease The absence of the mother from Marfan's disease The absence of the mother from anorexia nervosa The absence of the mother from chronic liver disease The absence of any type of lesion or wound at the intervention site Not having diabetes No allergy to Beneh ointment or no history of allergy to Beneh fruit

Exclusion criteria:

Reluctance to continue cooperation with the research unit Occurrence of hydramnios. Use of corticosteroid drugs (local and systematic). Use of any type of cream or oil on the abdominal area during the study Non-consecutive days during the study Rupture of fetal membranes, childbirth or termination of pregnancy for any reason Having gestational diabetes during the study

Age

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

Gender

Female

Phase

1-2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Allocation Concealment: envelopes will be prepared as many as the sample size (140). Half of the envelopes are for the intervention group and the other half for the control group. Inside the sealed envelopes, the type of group (intervention or control) will be specified on a sheet. Then the envelopes are closed. When the research units enter the research environment, an envelope will be randomly selected for them and the type of group to which the sample will be assigned will be revealed

Blinding (investigator's opinion)

Triple blinded

Blinding description

When preparing medicine and placebo, the pharmacist gives a code of one or two to their cans, and the code will remain hidden for the researcher, research unit and data analyst until the end of the analysis.

Placebo

Used

Assignment

Parallel

Other design features

On the first day of visit, some ointment is used on the inside of the forearm of the research unit, if no sensitivity occurs after 15 minutes, the severity of stretch marks, erythema and itching in the abdominal area, with the help of Davy's checklists and Kamini's checklists And it is checked.Then he explains how to use Beneh Ointment to the research unit and asks him to use 3 cm of 10% Oserin-based Beneh Ointment on the abdomen every day and emphasizes that during and after using Beneh Ointment on the abdomen don't massage and perform this procedure for 8 weeks in a row.Every 4 weeks, the research units must visit the research site and be evaluated by the researcher. After 8 consecutive weeks of intervention, immediately after the end of the intervention, the research units will return to the research environment to be examined again by the researcher.On the day after the end of the intervention, the Davi, Atwal and Kamini checklists are completed again by the researcher. The study and follow-up process in the control group (placebo) is the same as the intervention group, but instead of the placebo ointment (Oserin) that is in the cans It is similar to a can of ointment, they will use it.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Science

Street address

No. Azadi Ave., Kharazmi Blvd., Mashhad Town

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913131

Approval date

2023-10-17, 1402/07/25

Ethics committee reference number

IR.MUMS.NURSE.REC.1402.092

Health conditions studied

1

Description of health condition studied
stretch marks
ICD-10 code
O99.7
ICD-10 code description
Diseases of the skin and subcutaneous tissue complicating pregnancy, childbirth and the puerperium.

Primary outcomes

1

Description
Itching
Timepoint
First day of visit and the day after the end of the intervention
Method of measurement
Kamini checklist

2

Description
Erythema
Timepoint
First day of visit and the day after the end of the intervention
Method of measurement
Otwal checklist

3

Description
Striae
Timepoint
First day of visit and the day after the end of the intervention
Method of measurement
Davey checklist

Secondary outcomes

1

Description
Complication of the intervention
Timepoint
the day after the end of the intervention
Method of measurement
Copmlications checklist

2

Description
Satisfaction with the intervention
Timepoint
the day after the end of the intervention
Method of measurement
Intervention satisfaction questionnare

Intervention groups

1

Description
Intervention group: The intervention process in the intervention group is such that on the first day of the research units' visit to the research environment, the researcher uses some ointment on the skin of the inner forearm of the research unit, if after 15 minutes there is no itching, burning, Inflammation and discoloration did not occur (lack of drug sensitivity), the severity of striae, erythema and itching in the abdominal area, with the help of medication checklists (for this purpose, first, with the help of a surgical marker on the abdomen of the research unit, two perpendicular lines If their point of intersection is on the navel, he divides it into four equal parts and scores each part according to the checklist, then adds the total scores of the four parts together and determines the severity of striae according to the checklist, and completes the Kamini and Etowal checklists. Then he explains how to use Beneh ointment to the research unit and asks him to use 3 cm of 10% Oserin-based Beneh ointment on the stomach every day and emphasizes that during and after using the ointment Do not massage the abdomen and perform this procedure for 8 consecutive weeks. The researcher will follow up the use of the ointment once a week by the research units (both in the placebo group and in the intervention group) by telephone. . and asks them to fill in the checklist of the study process. In addition to this, the researcher forms a group in Eta, Yes or Rubika so that all the research units are placed in that group after entering the study, and they are reminded to use the drug daily. and asks the research units to visit the research site every 4 weeks and be evaluated by the researcher. After 8 consecutive weeks when the intervention was carried out, immediately on the day after the end of the intervention, the research units will return to the research environment to be re-evaluated by the researcher. The researcher should be examined. It should be noted that on the day after the end of the intervention, Davy, Atwal and Kamini checklists are completed again by the researcher. In addition to the examination checklists, questionnaires.
Category
Treatment - Drugs

2

Description
Control group: The study and follow-up process in the control group (placebo) is the same as the intervention group, but instead of Beneh ointment, they will use a placebo (Oserin) which is in the same cans as Beneh ointment. At the end of the intervention, the study process checklist will be received from the research unit.
Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Hazrat Abolfazl Zahedan Health Center

Full name of responsible person
Dr. Hosein Poor karami

Street address
No. 12, Dareh Pange Sheer Ave.,Abozar Blvd., Zahedan Town

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Fax

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TorkHesari4001@mums.ac.ir

Web page address
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2

Recruitment center

Name of recruitment center
Khadamat jame salamat emam sajad

Full name of responsible person
Dr.Sharzad Miri

Street address
No. 10, Emam Khomeini 19 Ave., Zahedan Town.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Research assistant of Mashhad University of Medical Sciences: Talaat Hkadiv Zadeh

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No. Azadi Ave., Kharazmi Blv., Mashhad Town

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TorkHesari4001@mums.ac.ir

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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
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
Mashhad University of Medical Sciences

Full name of responsible person
Dr. Kobra Mirzaei

Position
Consultant

Latest degree
Ph.D.

Other areas of specialty/work
Health Promotion

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Kobra Mirza Khani
Position
Consultant
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr.Kobra Mirza Khani
Position
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Other areas of specialty/work
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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
A study on the effect of ointment of pistacia atlantica oil on the prevention of stretch marks in primigravid wemon
When the data will become available and for how long
Available in the journal after publication
To whom data/document is available
All people who are interested in the article
Under which criteria data/document could be used
Promoting the method of preventing pregnancy stretch marks
From where data/document is obtainable
They send email to the corresponding author
What processes are involved for a request to access data/document
Explain the reasons for requesting the article in the email
Comments