

# 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 questionnaire

## 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

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9817784381

**Phone**

+98 54 3351 3902

**Fax****Email**

TorkHesari4001@mums.ac.ir

**Web page address**

<http://balad.ir>

### 2

#### Recruitment center

**Name of recruitment center**

Khadamat jame salamat imam sajad

**Full name of responsible person**

Dr.Sharzad Miri

**Street address**

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

**City**

زاهدان

**Province**

Sistan-va-Balouchestan

**Postal code**

9817784381

**Phone**

+98 54 3322 9684

**Fax****Email**

TorkHesari4001@mums.ac.ir

**Web page address**

<http://zaums.ac.ir>

## 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 Hkadv Zadeh

**Street address**

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

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913131

**Phone**

+98 51 3189 2105

**Email**

TorkHesari4001@mums.ac.ir

**Web page address**

<http://www.mums.ac.ir>

**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

**Street address**

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

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9117712390

**Phone**

+98 938 420 2290

**Email**

Mirzakhanik@mums.ac.ir

**Web page address**

<http://mums.ac.ir>

## 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**

Ph.D.

**Other areas of specialty/work**

Health Promotion

**Street address**

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

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9138813944

**Phone**

+98 51 3189 2105

**Fax****Email**

Mirzakanik@mums.ac.ir

**Web page address**

<http://www.mums.ac.ir>

**Province**

Razavi Khorasan

**Postal code**

9138813944

**Phone**

+98 51 3841 2081

**Email**

Mirzakanik@mums.ac.ir

**Web page address**

<http://www.mums.ac.ir>

**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 women

**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****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**

Consultant

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Health Promotion

**Street address**

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

**City**

Mashhad