

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluating the effect of aloe vera gel on prevention of SG in nulliparous woman

Protocol summary

Study aim

the effect of aloe vera gel on strea gravidarum prevention

Design

Clinical trial of three blinded with a control group with a random assignment on 90 nullipar women

Settings and conduct

In 1398, 90 women referred to two health centers affiliated with Shahid Beheshti University underwent surgery

Participants/Inclusion and exclusion criteria

Nulliparus Single pregnancy

Intervention groups

Group a received placebo Group b received aloe vera gel
Group c Control of non-receipt of any substance

Main outcome variables

Striae; Itching; Erythema

Phone

+98 21 7710 3995

Email address

bagherian.midwife94@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-01, 1398/03/11

Expected recruitment end date

2019-10-01, 1398/07/09

Actual recruitment start date

2019-06-05, 1398/03/15

Actual recruitment end date

2019-11-22, 1398/09/01

Trial completion date

2019-11-22, 1398/09/01

Scientific title

Evaluating the effect of aloe vera gel on prevention of SG in nulliparous woman

Public title

the effect of aloe vera gel on prevention of SG

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Nulliparus Single pregnancy Age:20-35 year

Exclusion criteria:

History of previous striae in the abdomen History of skin diseases

Age

From 20 years old to 35 years old

Gender

Female

Phase

3

Groups that have been masked

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190305042927N1**

Registration date: **2020-07-26, 1399/05/05**

Registration timing: **retrospective**

Last update: **2020-07-26, 1399/05/05**

Update count: **0**

Registration date

2020-07-26, 1399/05/05

Registrant information

Name

sahar bagherian

Name of organization / entity

Country

Iran (Islamic Republic of)

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Using random allocation software1.0, A simple random list of 3 groups with codes A, B and C for 90 participants was prepared and presented by a statistical consultant. The codes were placed in envelopes in the order of the list provided in the form of small cards by the research colleague, the lids of the envelopes were pasted and the envelopes were numbered in the order in the list obtained from the random assignment software.

Envelopes were given to the researcher who was doing the sampling. Eligible individuals were opened to enter the study envelope in order and the group was identified.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Researchers, participants, and data analyzers were not aware of the gel type. After preparing by the Pharmacognosy Center, the gels were named in the same package with codes A and B. At the end of the data analysis, the results were announced to the Pharmacognosy Center and the type of gel of each code was announced by that center. At the same time, the research colleague, who evaluated the outcome by observing and completing the observation checklist, did not know what the study groups (A, B, C) were receiving.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid beheshti University of Medical Sciences

Street address

Yemen St. - Shahid Abbas Arabi St. (Parvaneh) - Next to Taleghani Hospital - Shahid Beheshti University of Medical Sciences and Health Services - Headquarters Building 2- Floor 5- Deputy of Research and Technology

City

Tehran

Province

Tehran

Postal code

19839-63113

Approval date

2019-02-03, 1397/11/14

Ethics committee reference number

IR.SBMU.RETECH.REC.1397.1197

Health conditions studied

1

Description of health condition studied

Stria gravidarum

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Stria score in the Davy checklist

Timepoint

At the beginning of the study and 8 weeks after the intervention

Method of measurement

Davy method: The number of striae in each quarter of the abdomen is scored: "Score zero, no striae", "score one, number 2 striae", "score two, number 3-3 striae" and a total score of 0-0. . The final evaluation of striae severity is done in three groups: "zero without striae", "2-1 moderate striae" and "3-8 severe striae".

2

Description

Severity of striae pruritus

Timepoint

8 weeks after the intervention

Method of measurement

It was evaluated by Kamini method with a score of 4-0. Without itching "score 0", mild itching (1-2 times a day) "score 1", moderate itching without disruption of daily work (3-4 times a day) "score 2", severe itching (6- 5 times a day) annoying daily work "score 3" and severe itching throughout the day and disturbing work and sleep "score 4".

3

Description

Severity of striae erythema

Timepoint

8 weeks after the intervention

Method of measurement

By the way of Atval Assessed with a score of 3-0: no erythema "score 0", moderate erythema (bright red or pink) "score 1", symptomatic erythema (red) "score 2", severe erythema (purple) "score 3" Was considered

Secondary outcomes

empty

Intervention groups

1

Description

"Intervention group:" Receive aloe vera gel 75% from the 20th week of pregnancy to 28 pregnancies once a day in the amount of 5 grams or the equivalent of approximately 3 fingertips with 2 minutes of massage on the entire abdomen.

Category

Treatment - Drugs

2

Description

"Control group 1:" Receive placebo gel (Base gel without active ingredient) from the 20th week of pregnancy to 28 pregnancies once a day in the amount of 5 grams or approximately the equivalent of 3 fingertips with 2 minutes of massage on the entire abdomen.

Category

Placebo

3

Description

"Control group 2:" During the study (28-20 weeks of pregnancy) did not use any substance in the abdomen

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

East Health Center

Full name of responsible person

Ali Freidonfar

Street address

Shahid Babaei Highway

City

Tehran

Province

Tehran

Postal code

1778945181

Phone

+98 21 3349 1504

Email

bagherian.midwife94@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak

City

Tehran

Province

Tehran

Postal code

19839-63113

Phone

+98 21 2243 9781

Email

Mpajouhesh@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

1

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sahar Bagherian

Position

Midwifery Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Vali-Asr Avenue, Vali-Asr and Neiaiesh Highway Intersection, Opposite Rajae Hospital, Nursing and Midwifery School

City

Tehran

Province

Tehran

Postal code

1996835119

Phone

+98 21 8820 2512

Email
bagherian.midwife94@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Nourossadat Kariman
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
Vali-Asr Avenue, Vali-Asr and Neiaiesh Highway
Intersection, Opposite Rajaee Heart Hospital, School of
Nursing and Midwifery
City
Tehran
Province
Tehran
Postal code
1996835119
Phone
+98 21 8820 2512
Email
n_kariman@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Sahar Bagherian
Position
Midwifery Student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address

Vali-Asr and Neiaiesh Highway Intersection, Opposite
Rajaee Heart Hospital, Nursing and Midwifery School

City
Tehran
Province
Tehran
Postal code
1996835119
Phone
+98 21 8820 2512
Email
bagherian.midwife94@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Official request through corresponding researcher

When the data will become available and for how long

One year after article published.

To whom data/document is available

Universities and Research Centers

Under which criteria data/document could be used

Confidentiality and obtaining permission from the main researcher

From where data/document is obtainable

Corresponding authors' email

What processes are involved for a request to access data/document

After emailing and stating the reason for asking for the data

Comments