

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effects of hypericum perforatum ointment and lavender oil on the healing process of episiotomy wounds in nullipara women in Alavi Hospital in Ardabil

Protocol summary

Study aim

Comparison of the effects of hypericum perforatum ointment and lavender oil on the healing process of episiotomy wounds in nullipara women in Alavi Hospital in Ardabil

Design

This study will be performed as a randomized balloon experiment with 6-block method, without control group, with parallel groups, one-way blind, fuzzy 2-3 and with the participation of 100 women after episiotomy.

Settings and conduct

A total of 100 women who will undergo episiotomy in Alavi Hospital in Ardabil will be included in this study and will be randomly divided into two groups. Patients will receive the relevant medications after surgery and their results will be compared. It should be noted that the statistical consultant will be blind during the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria will include: vaginal delivery, Satisfaction to participate in the study and episiotomy surgery and exclusion criteria will be multiple pregnancies.

Intervention groups

Participants will be randomly assigned to this group 24 hours after episiotomy surgery; Then, they will apply hypericum perforatum ointment and lavender oil made by Abidi Pharmaceutical Company on their wound for 14 days (twice a day) and after 14 days, their wound condition will be examined with the help of clinical examination.

Main outcome variables

Wound healing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190325043107N28**

Registration date: **2022-04-26, 1401/02/06**

Registration timing: **registered_while_recruiting**

Last update: **2022-04-26, 1401/02/06**

Update count: **0**

Registration date

2022-04-26, 1401/02/06

Registrant information

Name

Mehdi Khanbabayi Gol

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 7054

Email address

khanbabayimehdi69@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-25, 1401/02/05

Expected recruitment end date

2022-06-15, 1401/03/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of hypericum perforatum ointment and lavender oil on the healing process of

episiotomy wounds in nullipara women in Alavi Hospital in Ardabil

Public title

Comparison of the effects of hypericum perforatum ointment and lavender oil on the healing process of episiotomy wounds

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Perform vaginal delivery
Perform episiotomy surgery
Satisfaction to participate in the study

Exclusion criteria:

Multiple pregnancies

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the block random division method (4 blocks) is used. One of the study partners, for whom blindness has not been performed, names the treatment of acne scars with the letters A and B. The researcher then distributes packages A and B among the patients referred to participate in the study by block random division method (4). Then, from the created blocks, enough blocks are randomly selected to reach the required sample size. How to create a random sequence using randomization was simple. To make a random sequence, we give possible blocks (6 blocks) from one to 6 numbers. Depending on the sample size, any number of 4 blocks that are needed will be used. Select the number of blocks from the table of random numbers and based on these numbers, the sequence of blocks in each group will be determined.

Blinding (investigator's opinion)

Single blinded

Blinding description

The statistical consultant of this project will be unaware of the type of grouping of participants; The final results will be delivered to the statistical consultant. As the statistical consultant will not be in the process of grouping the participants; Therefore, he is blind during the study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ardabil Islamic Azad University

Street address

Ardabil Islamic Azad University, Basij Ave

City

Ardabil

Province

East Azarbaijan

Postal code

5165665631

Approval date

2022-01-11, 1400/10/21

Ethics committee reference number

IR.IAU.ARDABIL.REC.1400.077

Health conditions studied

1

Description of health condition studied

Wound healing

ICD-10 code

O90.0

ICD-10 code description

Disruption of cesarean delivery wound

Primary outcomes

1

Description

Wound healing

Timepoint

Before and after treatment (14 days after treatment)

Method of measurement

Physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Participants will be randomly assigned to this group 24 hours after episiotomy surgery; Then, they will apply hypericum perforatum ointment made by Obidi Pharmaceutical Company on their wound for 14 days (twice a day) and after 14 days, their wound condition will be examined with the help of clinical examination.

Category

Treatment - Drugs

2**Description**

Intervention group: Participants will be randomly assigned to this group 24 hours after episiotomy surgery; Then, lavender oil made by Obidi Pharmaceutical Company will be rubbed on their wound for 14 days (twice a day) and after 14 days, the condition of their wound will be examined with the help of clinical examination.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Alavi Hospital

Full name of responsible person

Zahra Ghanbarian

Street address

Valiasr Ave, Alavi Hospital

City

Ardabil

Province

East Azarbaijan

Postal code

1995614331

Phone

+98 45 3372 8029

Email

doc_nsalehi@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Babak Gholami Nia

Street address

Ardabil Islamic Azad University, Basij Ave

City

Ardabil

Province

Ardabil

Postal code

598145693

Phone

+98 45 3372 8029

Email

info@iauardabil.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor****organization/entity?**

Yes

Title of funding source

Islamic Azad University

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**

Tabriz University of Medical Sciences

Full name of responsible person

Mehdi Khanbabayi Gol

Position

MSc in Nursing Education

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Imam Reza Hospital, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5981764863

Phone

+98 41 3334 7054

Fax**Email**

Khanbabayimehdi69@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Narges Salehi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Ardabil Islamic Azad University, Basij Ave

City

Ardabil

Province

Ardabil
Postal code
56985696
Phone
+98 45 3372 8029
Email
Narges_salehi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mehdi Khanbabayi Gol
Position
MSc in Nursing Education
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Imam Reza Hospital, Azadi Ave
City
Tabriz
Province
East Azarbaijan
Postal code
5981764863

Phone
+98 41 3334 7054
Fax
Email
Khanbabayimehdi69@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available