Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 perforatuma 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