Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation the effect of Silybum marianum ointment on episiotomy wound healing and pain intesity in primiparous women.

Protocol summary

Study aim
Determination of the effect of silybum marianum ointment on episiotomy wound healing and pain intesity in primiparous women.

Design
Clinical trials with control group, with parallel groups, blind, randomized.

Settings and conduct
This randomized double-blind controlled trial will be performed in Talesh shahid noorani hospital on primiparous women. The participants will be selected based on the inclusion criteria and allocated into groups A and B. Both groups will take ointments twice a day for 10 days. They will be checked at 12th hour, 5th and 10th day after childbirth and in each visit perineal pain intensity and wound healing will be evaluated usingVAS(Visual Analogue Scale) and REEDA (Redness(R),Edema (E),Ecchymosis(E),Discharge from the wound(D) ,Approximation of the perineal tissues) scoring scale. Finally at 10th day of postpartum, two groups will be compared for pain and wound healing.

Participants/Inclusion and exclusion criteria
Inclusion criteria: being primiparous; aged between 18 to 35 years; have a vaginal delivery with mediolateral episiotomy; singleton birth with cephalic presentation; literate; resident in Talesh; appropriate newborn weight (2500 to 4000 gr); lack medical disease history; no allergies to topical drugs; No long-term rupture membrane more than 24 hours; No addiction history; BMI between 18.5-29.9; no manual removal of placenta. Exclusion criteria:lack of regular or correct ointment using;Unwillingness to continue studying;Excessive bleeding occurs in the first 24 hours of delivery; having sexual intercourse during the first 10 days after birth.

Intervention groups
Intervention group:silybum marianum ointmen uses topically one finger amount on episiotomy wounds twice for 10 days. In control group; placebo cream uses topically one finger amount on episiotomy wounds twice for 10 days.

Main outcome variables
wound healing of episiotomy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181110041603N1**
Registration date: **2019-08-10, 1398/05/19**
Registration timing: **registered_while_recruiting**

Last update: **2019-08-10, 1398/05/19**
Update count: **0**

Registration date
2019-08-10, 1398/05/19

Registrant information

Name
ELMIRA TOOMARY

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8877 0061

Email address
elmira.toomary68@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-08-05, 1398/05/14

Expected recruitment end date
2019-10-06, 1398/07/14

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of Silybum marianum ointment on episiotomy wound healing and pain intesity in primiparous women.

Public title

Effect of Silybum marianum ointment on wound healing and episiotomy pain in primiparous women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Being primiparous Aged between 18 to 35 years. BMI between 18.5-29.9. Resident in Talesh. literate. Singleton birth with cephalic presentation Appropriate newborn weight(2500 to 4000 gr) have a vaginal delivery with mediolateral episiotomy. No long-term rupture membrane more than 24 hours. lack medical disease history. Perineal swelling did not occur immediately after episiotomy. No addiction history No allergies to topical drugs. No manual removal of placenta

Exclusion criteria:

Mother's reluctance to continue studying. Mother does not use silybum marianum ointment regularly and in accordance with the instructions. Mother should not wash episiotomy and in accordance with the order (less than twice a day). Mother has sex within 10 days of delivery. Perineal has been tampered with after any episiotomy repair. Excessive bleeding occurs in the first 24 hours of delivery.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Random numbers will be used to randomize and assign individuals to groups; the randomization using Excel software is as follows: First, in a column, the groups are entered as A, B, and below, since the number of samples in each group is 45 (including sample loss), therefore, 45, B, A should be repeatedly and regularly be. In the opposite column, random numbers are generated using the RAND command. In the next step, using the order command, random numbers are generated from small to large or vice versa, which makes the order of groups A, B change. By using the new order, people are assigned to different groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blind technique will be double-blind, and the investigator and none of the patients will be aware of the type of medication. The drugs are labeled with A, B, C and D labels and given to patients. To conceal the allocation of individuals, the drugs are numbered in the same boxes, depending on the order of allocation. Interventions are stored in closed packet envelopes and are periodically numbered. To hide the allocation of individuals, envelopes are rotated periodically and only after the name and other characteristics of the participant are written on the appropriate envelope.

Placebo

Used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق دانشگاه علوم پزشکی و خدمات بهداشتی درمانی شهید بهشتی

Street address

Tehran, Shahid Abbas poor Street

City

Tehran

Province

Tehran

Postal code

193954719

Approval date

2019-04-14, 1398/01/25

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1398.030

Health conditions studied

1

Description of health condition studied

Episiotomy

ICD-10 code

090/1

ICD-10 code description

Disruption of perineal obstetric wound

Primary outcomes

1

Description
Intensity of episiotomy pain
Timepoint
before intervention, 12 hours, 5 and 10 days postpartum.
Method of measurement
Visual Analogue Scale (VAS)

2

Description
wound healing of episiotomy
Timepoint
before intervention, 12 hours, 5 and 10 days postpartum.
Method of measurement
REEDA scale

Secondary outcomes

1

Description
Complete episiotomy repair
Timepoint
10 day after delivery
Method of measurement
REEDA scale

Intervention groups

1

Description
Intervention group: Silybum marianum ointment (produced in Shahid Beheshti pharmacy faculty) uses topically one finger amount (2cm) on episiotomy wounds twice for 10 days.
Category
Treatment - Drugs

2

Description
Control group: ; placebo ointment (produced in Shahid Beheshti pharmacy faculty) uses topically one finger amount (2cm) on episiotomy wounds twice for 10 days.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Noorani Hospital
Full name of responsible person
Elmira Toumary
Street address
Shahid Beheshti Street,Talesh,Gilan
City
Talesh
Province
Guilan
Postal code
4371937916
Phone
+98 13 4422 1102
Fax
Email
Nooranih@gums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
vice chancellor for research of school of nursing and midwifery Shahid Beheshti university of medic
Street address
Intersection of Prayer - In front of Shahid Rajaee Heart Hospital - Faculty of Nursing and Midwifery - Valiasr St.-Tehran
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 8865 5366
Email
sbnmf@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
vice chancellor for research of school of nursing and midwifery Shahid Beheshti university of medic
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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr Sepideh Hajian

Position
Phd of Midwifery
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
School of Nursing and Midwifery, Niayesh Highway, Valiasr St, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 8865 5366
Email
s.hajian@sbmu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr Sepideh Hajian
Position
PHD of midwifery
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
chool of Nursing and Midwifery of Shahid Beheshti University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 8865 5366
Email
s.hajian@sbmu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Elmira Toumary
Position
Student of master Midwifery
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
School of Nursing and Midwifery, Valiasr St, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 8865 5366
Email
Elmira.toomary68@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