# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

27 Jul 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