

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

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

#### Protocol summary

##### Study aim

Determination of the effect of silybum marianum ointment on episiotomy wound healing and pain intensity 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 using VAS (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 ointment 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 intensity 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 Rajaei 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@sbm.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**

School 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@sbm.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