

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Comparison of the effect of Malva sylvestris L extract ointment and placebo on pain intensity and episiotomy wound healing in primiparous women

Protocol summary

Study aim

1. Determining and comparing the amount of pain and episiotomy wound healing before intervention and in the first 24 hours after delivery and on days 5 and 10 postpartum in Malva sylvestris L extract ointment and placebo ointment group with Each other. 2. Determine the side effects of consuming Malva sylvestris L ointment.

Design

A clinical trial with control group, with parallel groups, triple blind, randomization using random allocation software. Phase three Trial and The sample size is 112 people.

Settings and conduct

This research is a kind of three-blind clinical trial that will be conducted in Mahdiyeh hospital in Tehran. The ointments of Malva-sylvestris-L extract and placebo are made with the same packaging and with different codes that the pharmacist will be aware of. The researcher, the patient and the statistics do not know the contents of the drugs. The participants will randomly choose one of the coded cards according to the drug code and will be placed in one of the two intervention or control groups. The ointments will be used twice a day for 10 days.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Primiparous women giving birth; Ages 18 to 35 years; Being Iranian; Gestational age between 37 and 42 weeks; Having single fetal cephalic presentation. Exclusion criteria: Amniotic sac rupture more than 24 hours; Having hematoma; fever and puerperal infection after delivery

Intervention groups

Intervention group: Malva sylvestris L 3% ointment is applied Twice daily, 2 centimeters (cm), for 10 days on episiotomy ulcer. Control group: Placebo ointment Twice daily, 2 cm, is applied on episiotomy ulcer for 10 days. Initial assessment of pain intensity and wound healing is

done 24 hours after the intervention and then on the 5th and 10th days.

Main outcome variables

Pain; Redness; Edema; Ecchymosis; Discharge from the wound; Approximation of the perineal tissue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100130003226N19**

Registration date: **2022-11-28, 1401/09/07**

Registration timing: **prospective**

Last update: **2022-11-28, 1401/09/07**

Update count: **0**

Registration date

2022-11-28, 1401/09/07

Registrant information

Name

Mahrokh Dolatian

Name of organization / entity

Shahid Beheshti University of Medical Scenices

Country

Iran (Islamic Republic of)

Phone

+98 21 8820 2512

Email address

m_dolatian@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-07-22, 1402/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Malva sylvestris L extract ointment and placebo on pain intensity and episiotomy wound healing in primiparous women

Public title

Evaluation the effect of Malva sylvestris L extract ointment on pain intensity and incision of during delivery wound healing in primiparous women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Married women aged 18 to 35 years primiparous Being Iranian Gestational age between 37 to 42 weeks No smoking, alcohol and drugs Being literate in reading and writing Having a single fetus with cephalic presentation Fetal weight between 2500 and 4000 gr Body Mass Index (BMI) between 18.5 and 25 Vaginal delivery with mediolateral episiotomy The normality of the first, second and third stages of labor

Exclusion criteria:

Amniotic sac rupture more than 24 hours Allergy to Malva sylvestris L ointment Having fever, puerperal infection and hematoma Infant hospitalization at Neonatal Intensive Care Unit Having postpartum hemorrhoids or fissures Having sex in the first ten days after delivery

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **112**

Randomization (investigator's opinion)

Randomized

Randomization description

It is available (simple) and goal based. In this way, all patients who are eligible for the study will be screened. The delivery of medicine to the patients in a box containing several cards that are evenly written in the English alphabet "A and B" with the placebo and Malva sylvestris L ointment code (researcher unaware of the content of the ointments) we match and patients randomly choose a card and receive the medicine according to the letters on the card.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This study is a kind of triple-blind randomized controlled clinical trial. At the diagnostic stage, the demographic forms and obstetric and delivery questionnaire are not completed and the patient's name is not written. At the stage of giving medicine to the patient, a placebo and Malva-sylvestris-L ointment are marked with the English letter A and B coded by the pharmacist. The researcher is not aware of the contents of the ointments and the patient also randomly selects one of the placebos or Malva-sylvestris-L ointments the statistic professor is also unaware of the intervention and control groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Pharmacy, Nursing and Midwifery Faculties of Shahid Beheshti University of Medic

Street address

Block A, 13th floor, Central Headquarters of the Ministry of Health, Treatment and Medical Education, Simai Iran Street, between South Flamak and Zarafshan, Quds Town (West), Tehran.

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2022-10-31, 1401/08/09

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1401.160

Health conditions studied

1

Description of health condition studied

Episiotomy

ICD-10 code

O70

ICD-10 code description

Perineal laceration during delivery

Primary outcomes

1

Description

Episiotomy wound healing

Timepoint

Before the intervention, the first 24 hours, 5 and 10 days after treatment

Method of measurement

REEDA scale assess 5 items such as Redness, Edema, Ecchymoses, Discharge from the wound and Approximation of the perineal tissues.

2

Description

Episiotomy wound pain intensity

Timepoint

Before the intervention, the first 24 hours, 5 and 10 days after treatment

Method of measurement

The visual pain scale (VAS) is a tool for measuring the intensity of pain, which is a 10 cm ruler with eleven numbers.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: Uses 3% Malva sylvestris L ointment for 10 days (daily) at a rate of two centimeters, on episiotomy wound. This ointment is produced at the Faculty of Pharmacy of Shahid Beheshti University of Medical Sciences. Initial assessment of pain intensity and wound healing is done before the intervention, 24 hours after the intervention and then on the fifth and tenth days.

Category

Treatment - Drugs

2

Description

Control group: Control group: Use placebo ointment (quite similar to Malva sylvestris L ointment) for 2 days (daily) at 2 cm, on episiotomy ulcer. This ointment is produced at the Faculty of Pharmacy of Shahid Beheshti University of Medical Sciences. Initial assessment of pain intensity and wound healing is done before the intervention, 24 hours after the intervention and then on the fifth and tenth days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdiyeh hospital

Full name of responsible person

Zohreh Jafari

Street address

Shahid Rajab Nia St., Shihgar Khane Alley, Shoush Square, Fedaiyan Islam St., Tehran

City

Tehran

Province

Tehran

Postal code

1185817311

Phone

+98 21 5506 2628

Fax

Email

mahdiyeh_hospital@sbmu.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr.Afshin Zarghi

Street address

University Building No. 2 of ShahidBeheshti University of Medical Sciences, Parvaneh Str., Yemeni Ave, Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2243 9781

Fax

+98 21 2243 9981

Email

zarghi@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Shahid Beheshti University of Medical Sciences

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

Postal code
1985717443
Phone
+98 21 8865 5366
Email
mhdolatian@gmail.com

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mahrokh Dolatian
Position
Ph.D.
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
School of Nursing and Gynecology Department, In front of Shaheed Rajaei Heart Hospital, The intersection of Niayesh, Vali asr street, Tehran
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 8865 5366
Email
mhdolatian@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Mahrokh Dolatian
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Faculty of Nursing & Midwifery, In front of Shahid Rajai Hospital, Niayesh Expressway, Valiasr St, District3, Tehran.
City
Tehran
Province
Tehran

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Zohreh Jafari
Position
Masters Student of Midwifery
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Faculty of Nursing & Midwifery, In front of Shahid Rajai Hospital, Niayesh Intersection, Valiasr St, Tehran.
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 8865 5366
Email
zohre.jafari76@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