Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of Mummy on the Intensity of Episiotomy Pain and Wound Healing in Primiparous Afghan Women.

Protocol summary

Study aim
The effect of Mummy on the Intensity of Episiotomy Pain and Wound Healing in Afghan Women

Design
The clinical trial with control and placebo, triple-blinded, randomized phase 3, on 66 patients. Randomization will be done using the website www.randomization.ir

Settings and conduct
A randomized, triple-blind, two-group clinical trial will be conducted on 66 Afghan women referring to Hazrat-e-Om-Albanin (AS) and Shahid Hashemi Nejad hospitals in Mashhad. For the determination of the effect of the herbal cream on the intensity of pain associated with episiotomy in primiparous Afghan women and its impact on episiotomy wound healing, Participants will receive either the herbal cream or placebo three times a day for 10 days, starting two hours after episiotomy. Pain severity will be assessed before intervention, on the first, fifth, and tenth day's post-intervention using a shortened McGill Pain Questionnaire in a seated position. Wound healing progress will be evaluated on the first, fifth, and tenth days postpartum using the Rida scale in the lithotomy position.

Participants/Inclusion and exclusion criteria
Afghan women aged18-45,residing in Mashhad, literacy, Primipara, Normal delivery, Single, full-term, and healthy baby, Body mass index18.5to24.9,Mediolateral episiotomy without complication(incision size more than6cm) ,Baby weight between 2500-4000g.Exclusion criteria:Using chemical or herbal medications effective in reducing pain or improving the healing of episiotomy wounds, not using the cream in two or more sessions the entire period, developing metritis at the episiotomy site, reopening of episiotomy stitches, developing any complication during postpartum,etc.

Intervention groups
Participants will be administered mummy cream or placebo, 2 hours after episiotomy three times daily for 10days.

Main outcome variables
Intensity of episiotomy pain and wound healing in women

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240318061331N2**
Registration date: **2024-05-12, 1403/02/23**
Registration timing: **prospective**

Last update: **2024-05-12, 1403/02/23**
Update count: **0**

Registration date
2024-05-12, 1403/02/23

Registrant information

Name
Hamideh Yazdimoghaddam

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-06-21, 1403/04/01

Expected recruitment end date
2025-09-08, 1404/06/17

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Mummy on the Intensity of Episiotomy Pain and Wound Healing in Primiparous Afghan Women.

Public title

The effect of Mummy on Intensity of Episiotomy Pain and Wound Healing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Afghan women aged 18-45 residing in Mashhad Reading and writing literacy Primipara Normal delivery Single, full-term, and healthy baby Body mass index 18.5 to 24.9 Mediolateral episiotomy without any instances of rupture, hematoma, and extension of the incision (incision size more than 6cm) Baby weight between 2500-4000 g

Exclusion criteria:

Using chemical or herbal medications effective in reducing pain or improving the healing of episiotomy wounds Not using the cream in two or more sessions throughout the entire period Persistent constipation Developing metritis or infection at the episiotomy site Reopening of episiotomy stitches (of course its amount is checked and recorded in two groups) Intercourse during the study Experiencing any complications during the postpartum period Genital skin disease such as vestibulitis, vulval dystrophy Diseases such as (chronic systemic diseases, heart disease, coagulation disorder, diabetes, kidney and lung disease, anemia, malnutrition, neurological and psychiatric disorders, etc.) Using medications effective in wound healing such as anticoagulants, antidepressants, antiepileptic, immunosuppressant Drug abuse, psychotropic drugs, alcohol, and tobacco addiction Using analgesics to reduce labor pain, experiencing childbirth Complications during labor stages Experiencing neonatal complications during labor stages Having a history of sensitivity to mummy according to the self-report of the mother Having lesions such as genital warts and genital herpes in the perineum, vagina, and perineum

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling will be conducted using a convenience sampling, with samples being allocated to two groups via random assignment facilitated by software. The random allocation of women into the cream and placebo groups will be achieved through random sequence generation by the website www.randomization .com and employing random blocking.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Mummy cream and placebo will be poured into completely identical tubes. The creams will be similar in shape, color, and packaging. Both the mummy cream and placebo are assigned unique codes, which are determined through a random selection process and only the supervising pharmacist will be aware of the assigned codes to the creams.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

School of Nursing and Midwifery, Shahid Dr. Kharazmi Educational Complex, University Campus, East Gate of Ferdowsi University of Mashhad, Azadi Square, , Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2024-03-04, 1402/12/14

Ethics committee reference number

IR.MUMS.NURSE.REC.1402.137

Health conditions studied

1

Description of health condition studied

The Intensity of Episiotomy Pain and Wound Healing

ICD-10 code

O90.89

ICD-10 code description

Other complications of the puerperium

Primary outcomes

1

Description
The Intensity of Episiotomy Pain
Timepoint
Assessment of pain intensity will be conducted prior to the initiation of the intervention, as well as on the first, fifth, and tenth days following the intervention.
Method of measurement
Pain intensity evaluation will be carried out prior to the intervention, as well as on the first, fifth, and tenth day post-intervention, using the shortened McGill pain questionnaire while in a sitting position.

2

Description
Episiotomy wound healing
Timepoint
Evaluation of wound healing on the first, fifth, and tenth day following the intervention involving the application of mummy cream.
Method of measurement
Wound healing assessment will be done on the first, fifth, and tenth day after delivery, utilizing the Rida scale while in the lithotomy position.

Secondary outcomes

empty

Intervention groups

1

Description
After child birth, the researcher will measure the length and depth of the episiotomy incision by utilizing a sterile swab that was marked with ruler measurements to accurately measure and record its length and depth. The mother will receive personalized instructions on perennial care, which involved gently cleansing the perineum from front to back using warm water, followed by the use of a clean cloth before applying the cream. She is also instructed to wash and dry her hands with water and liquid soap before applying the cream. The mummy cream was then applied to the episiotomy, with a total of 2 to 3 cm applied twice daily (every 12 hours) for a duration of 10 days.
Category
Treatment - Other

2

Description
After child birth, the researcher will measure the length and depth of the episiotomy incision by utilizing a sterile swab that was marked with ruler measurements to accurately measure and record its length and depth. The mother will receive personalized instructions on perineal care, which involved gently cleansing the perineum from front to back using warm water, followed by the use of a clean cloth before applying the cream. She is also instructed to wash and dry her hands with water and liquid soap before applying the cream. The placebo cream was then applied to the episiotomy, with a total of 2 to 3 cm applied twice daily (every 12 hours) for a duration of 10 days
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Umm al-Binin Hospital (s)
Full name of responsible person
Nahid Sahebdel
Street address
Corner of Ayatollah Behjat 16, Zarineh Crossroad, Mashhad, Razavi Khorasan, Iran
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Razavi Khorasan
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2

Recruitment center
Name of recruitment center
Mashhad Shahid Hashminejad Hospital
Full name of responsible person
Seyyed Mohamad Mousavi
Street address
End of Aburihan Blvd, Mufteh St., Mashhad, Razavi Khorasan, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person

Mahmoud Mohammadzadeh Shabestari

Street address

Eastern Door of University Campus, Azadi Square, Mashhad, Razavi Khorasan, Iran

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Email

ShabestariMM@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Fatemeh Zahra Karimi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

School of Nursing and Midwifery, Shahid Dr. Kharazmi Educational Complex, University Campus, East Gate of Ferdowsi University of Mashhad, Azadi Square , Razavi Khorasan, Mashhad, Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Fatemeh Zahra Karimi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Fatemeh Zahra Karimi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

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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