# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## The effect of alpha ointment (fundermol) on wound healing and pain episiotomy in primiparous women

## Protocol summary


**Summary**

This study is a double-blind clinical trial, aiming to evaluate the effects of the Alpha Ointment on wound healing and pain relief of episiotomy in nulliparous women. Episiotomy means cutting the surface muscles, skin and the vaginal wall. At the second stage of delivery, it is given to the perineum tissue to widen the output valve at the time of birth. Alpha Ointment is purely herbal. The active ingredient of this ointment is Lawson (2-hydroxy-1,4-naphthoquinone), which is obtained from henna. The combination of this medication includes Lawson (active ingredient), Honey (sucker), flavonoids, polyunsaturated fatty acids and curcumin (Curcuma effective substance). Thirty primiparous women referring to Om-Albanin Hospital for normal delivery are selected as samples after gaining the consent of the patients and controlling the inclusion and exclusion criteria. For the first time, three hours after the completion of episiotomy recovery, and later washing the perineal with saline serum and drying, amount of a knuckle of medication or placebo is used with latex gloves on the wound, in a way that it covers the whole surface. Before intervention and giving tranquilizer, the patient's perineal pain is measured through McGill's shortened questionnaire. The time of ointment usage in both groups is three times a day, which continues for ten days. On the first, fifth, and tenth day, and in case of incomplete wound healing on the 14th day, wound appearance is checked via the REEDA tool.


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2015100524371N1**
Registration date: **2016-06-22, 1395/04/02**
Registration timing: **retrospective**
Last update:
Update count: **0**

**Registration date**

2016-06-22, 1395/04/02


**Registrant information**

**Name**
Mozhdeh Navi Nezhad
**Name of organization / entity**
Mashhad University of Medical Sciences
**Country**
Iran (Islamic Republic of)
**Phone**
+98 51 4423 3808
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**Recruitment status**

**Recruitment complete**


**Funding source**

Mashhad University of Medical Sciences


**Expected recruitment start date**

2016-01-17, 1394/10/27

**Expected recruitment end date**

2016-06-04, 1395/03/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of alpha ointment (fundermol) on wound healing and pain episiotomy in primiparous women

**Public title**

The effect of alpha ointment (fundermol) on wound healing and pain episiotomy in primiparous women

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: nulliparous women aged 18-35 years old living in the city of Mashhad, Iran; at least having the ability to read and write; normal body mass index ranging ; non-smoking and no drug dependence; no history of disease impaired wound healing; not using drugs effecting on wound healing; lack of symptomatic infections of the vagina and vulva , anal lesions; vulva and perineum on admission; the lack of apparent anomalies in the newborn. No rectocel, cystocele severe (grade 2 or higher), wall or mass in the vaginal, use of acetaminophen suppository in 6 hours before delivery; no history of vaginal reconstructive surgery on the Vagina and urethra Exclusion criteria: there interfere with the progress of labor; prolonged second stage of labor longer than 2 hours; delivery devices (vacuum, forceps); extend the length of the incision or there tear except episiotomy tear; infant hospitalization in the NICU; abnormal vaginal bleeding; shoulder dystocia (leading to the maneuvers other than Robert Mack); manual removal of placenta; hematoma; having intercourse to the end of the study (15 days postpartum); curettage procedure the first 24 hours after birth; the third stage of labor longer than 30 minutes; no need for episiotomy; not use the cream on a regular; puerperal fever; complications resulting from the use of alpha ointment cream

**Age**

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

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

The research units randomized to 2 groups by throwing a coin were allocated to Alpha ointment and placebo. Double-blind study is done in such a way that patients and researchers were not aware the type of drug available in cans Code. Samples were selected through using simple random sampling.

## 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, Doktora Intersection , Mashhad

**City**

Mashhad

**Postal code**

**Approval date**

2015-10-28, 1394/08/06

**Ethics committee reference number**

ir.mums.rec.1394.582

## Health conditions studied

**1**

**Description of health condition studied**

wound healing of episiotomy , pain of episiotomy

**ICD-10 code**

O90.1

**ICD-10 code description**

Disruption of perineal obstetric wound

## Primary outcomes

**1**

**Description**

Wound healing of episiotomy

**Timepoint**

Days the first, fifth and tenth after delivry

**Method of measurement**

Reeda Scale

**2**

**Description**

Pain of episiotomy

**Timepoint**

Days the first, fifth and tenth after delivery

**Method of measurement**

McGill Pain Questionnaire short

## Secondary outcomes

**1**

**Description**

Wound healing of episiotomy

**Timepoint**

Days the first, fifth and tenth after delivery

**Method of measurement**

Reeda scale

**2**

**Description**

Pain of episiotomy

**Timepoint**

Days the first, fifth and tenth after delivery

**Method of measurement**

McGill Pain Questionnaire short

## Intervention groups

### 1

**Description**

In the intervention group , after washing perineal with normal saline serum and drying it, put Alpha ointment as much as a Thumbnail for the area The sutures, So that completely cover the wound surface and do that three times a day to ten days did.

**Category**

Treatment - Drugs

### 2

**Description**

In the control group, after washing perineal with normal saline serum and drying it, put placebo ointment as much as a Thumbnail for the area The sutures, So that completely cover the wound surface and do that three times a day to ten days did.

**Category**

Placebo

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Specialized Women's Hospital, Mashhad Omolbanin (SA)

**Full name of responsible person**

**Street address**

**City**

Mashhad

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Vice chancellor for research, Mashhad University of Medical Sciences

**Street address**

School of Nursing and Midwifery, Doktora Intersection

**City**

Mashhad

**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**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

**Contact**

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## Person responsible for scientific inquiries

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
*empty*
**Study Protocol**
*empty*
**Statistical Analysis Plan**
*empty*
**Informed Consent Form**
*empty*
**Clinical Study Report**
*empty*
**Analytic Code**
*empty*
**Data Dictionary**
*empty*