

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of raspberry ointment on epistolary ulcer in Primal woman

#### Protocol summary

##### Study aim

Effect of raspberry ointment on episiotomy ulcer healing

##### Design

Clinical trial. Controlling group. Community-based and pragmatic. With parallel groups.double blinded

##### Settings and conduct

Al-Hadi Hospital and Health Center on days 7, 10, 14 after delivery by the researcher

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Iranian race and resident of Shushtar Primipara with age between 18-35 years Have a reading and writing literacy Term pregnancy with live birth defects Baby weight between 4000-2500 grams Body mass index ranging from 19.9-9.9 Non-use of effective drugs on wound healing by the mother without the risk of damaging diseases. Wound healing without having a rupture of the membrane for more than 18 hours. No postpartum hemorrhage No pairing out of hand The lack of perineal hematoma Failure to reintroduce perineal after delivery Absence of newborn bedridden or neonatal anomalies Not having cystosclerosis and severe rectus No history of reconstructive surgery on the vagina and midwifery Exit criteria: Disturbances in the progress of labor The length of the second stage of delivery is more than 2 hours Abnormal vaginal bleeding Perform curettage or anesthesia in the first 24 hours after delivery Presence of fever Episiotomy site infection Need to suture again with episiotomy Use of drugs that affect wound healing during the study

##### Intervention groups

Primiparous women who have used a raspberry ointment in episiotomy

##### Main outcome variables

Red. Edema. Defecation. Spread from the wound. Double wound spacing. Pain in the episiotomy

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20181007041267N1**

Registration date: **2019-08-07, 1398/05/16**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-08-07, 1398/05/16**

Update count: **0**

#### Registration date

2019-08-07, 1398/05/16

#### Registrant information

##### Name

forough boustani

##### Name of organization / entity

Shoushtar

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3621 9254

##### Email address

stu.boostani72@gmail.com

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2019-01-11, 1397/10/21

#### Expected recruitment end date

2020-01-11, 1398/10/21

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of raspberry ointment on epistolary ulcer in Primal woman

#### Public title

Effect of raspberry on episiotomy

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Iranian race and resident of Shushtar Primipara with age between 18-35 years Have a reading and writing literacy Term pregnancy with live birth defects Baby weight between 4000-2500 grams Body mass index ranging from 29.9 to 19.9 No use of effective medications for mother's wound healing No rupture of the bag for more than 18 hours No postpartum hemorrhage No pairing out of hand The lack of perineal hematoma Failure to reintroduce perineal after delivery Absence of newborn bedridden or neonatal anomalies Not having cystocele and severe rectus in the vagina No history of reconstructive surgery on the vagina and midwifery

### Exclusion criteria:

Disturbances in the progress of labor The length of the second stage of delivery is more than 2 hours Abnormal vaginal bleeding Perform curettage or anesthesia in the first 24 hours after delivery Presence of fever Episiotomy site infection Need to suture again with episiotomy Use of drugs that affect wound healing during the study Do not use ointment regularly and in accordance with instructions Sensitization to the desired ointment Unwillingness to continue to participate in the study Have sex during the first five days after delivery Failure to go to the clinic of the hospital or the nearest clinic to the person's home on the seventh, tenth and fourteenth day after childbirth Existence of extension of cutting length Abnormal vaginal bleeding Shoulder Dystopia

## Age

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

## Gender

Female

## Phase

3

## Groups that have been masked

- Investigator
- Data analyser

## Sample size

Target sample size: **120**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The sampling method is targeted to female patients referring to Al Hadi hospital in Shoushtar. After reviewing the criteria for entering the study, allocation of individuals to groups is done using random block assignment.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Blinding is related to research and analysis. In order to blindness, the random allocation of the units study will be done in two groups of control and intervention and will be followed by the midwife.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of shoushtar faculty medical of sciences

##### Street address

shoushtar faculty medical of sciences

##### City

shoushtar

##### Province

Khuzestan

##### Postal code

6451675943

#### Approval date

2016-11-05, 1395/08/15

#### Ethics committee reference number

IR.SHOUSHTAR.REC.1397.003

## Health conditions studied

### 1

#### Description of health condition studied

episiotomy sore

#### ICD-10 code

o90.1

#### ICD-10 code description

Disruption of perineal obstetric wound

## Primary outcomes

### 1

#### Description

Effect of raspberry ointment on episiotomy ulcer

#### Timepoint

On days 7.10.14 after delivery

#### Method of measurement

Questionnaire by Rida and Lazar Waz

## Secondary outcomes

### 1

#### Description

The effect of raspberry ointment on the reduction of episiotomy redness Effect of raspberry ointment on decreasing episiotomy size Reduction of episiotomy bruises of raspberry ointment on reducing the amount of secretion from episiotomy ulcer Ointment of raspberry on reducing the amount of two-edges of episiotomy ulcer of

raspberry ointment on reducing the degree of score of the pain of episiotomy ulcers

#### **Timepoint**

On days 7.10.14 after delivery

#### **Method of measurement**

Visual Analogue Scale and analyse the Redness, Oedema, Ecchymosis, Discharge, Approximation

## **Intervention groups**

### **1**

#### **Description**

"Intervention group:" The raspberry ointment was after the pharmaceutical stages prepared and selected as an intervention medicine. It will be in empty tubes. After washing and drying the perineum, phalange ointment put on the perina area, So that they cover it and use a clean sanitary pad after 1-2 minutes, and continue to do this 2 times a day, morning and night before bedtime until the 14th day after childbirth. Exit from the wound, severe pain in the perineum, excessive periosteum, perineal area, burning, itching, stiffness and dandruff in the wound area with the researcher to investigate and take necessary action. Also, in the form of the registration of side effects, based on the questions asked, Note the complication. The status of mothers' episiotomy improvement during the 7th, 10th and 14th days after delivery will be investigated by the researcher based on the objective evaluation of the REEDA wound and the VAZE visual inspection tool.

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

control group: Use of routine hospital practice And without any additional action(washed with diluted iodine) twice a day for 1 week and The status of mothers' episiotomy improvement during the 7th, 10th and 14th days after delivery will be investigated by the researcher based on the objective evaluation of the REEDA wound and the VAZE visual inspection t

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Al-hadi Hospital. Health Center

##### **Full name of responsible person**

Forough Boustani

##### **Street address**

Shoushtar faculty Medical of Sciences. Al Hadi hospital. BLV Rajae

##### **City**

Shoushtar

##### **Province**

Khouzestan

##### **Postal code**

6451675943

##### **Phone**

+98 61 3622 9325

##### **Email**

stu.boostani72@gmail.com

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Ahvaz University of Medical Sciences

##### **Full name of responsible person**

Mojtaba Kalantar

##### **Street address**

Shoushtar faculty Medical of Sciences. Al Hadi hospital. BLV Rajae

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#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Ahvaz 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**

Shoushtar School of Medical Sciences

##### **Full name of responsible person**

Forough Boustani

##### **Position**

Health personnel

##### **Latest degree**

Bachelor

##### **Other areas of specialty/work**

Midwifery

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shoushtar School of Medical Sciences

**Full name of responsible person**

Forough Boustani

**Position**

Health personnel

**Latest degree**

Bachelor

**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

Forough Boustani

**Position**

Health personnel

**Latest degree**

Bachelor

**Other areas of specialty/work**

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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**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Parts related to the main consequence

**When the data will become available and for how long**

6 months after printing results

**To whom data/document is available**

All people

**Under which criteria data/document could be used**

In order to have a clinical trial after the publication of the article

**From where data/document is obtainable**

Forough Boustani 0098 9011730046

**What processes are involved for a request to access data/document**

Three years after the publication of the article

**Comments**