

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 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

Khouzestan

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

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Phone

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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

Street address

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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**

Shoushtar School of Medical Sciences

Full name of responsible person

Forough Boustani

Position

Health personnel

Latest degree

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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