Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 Rajaee

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Shoushtar

Province

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Postal code

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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

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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
Midwifery
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Person responsible for updating data

Contact
Name of organization / entity
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Full name of responsible person
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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