Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation the effect of mastic Arnebia euchroma Ointment resin on wound healing and perineal pain after childbirth in women had episiotomy in alborz in 1397

Protocol summary

Study aim
To determine the effect of mastic Arnebia euchroma Ointment on pain intensity and healing of episiotomy in nulliparous women in Alborz in 2018.

Design
Design, The study population consists of nulliparous women referred to the maternity hospital and had episiotomy. This is a single-blind randomized clinical trial.

Settings and conduct
Setting and conduct, The sample size consists of 190 people. They will be randomly put into the two groups of control and intervention according to the inclusion criteria. Block randomization method will be used for random sampling.

Participants/Inclusion and exclusion criteria
Inclusion criteria: no systemic disease; no use of immunosuppressant drugs and corticosteroids; no acute disease and constipation Exclusion criteria: history of mental and personality illness; difficult delivery; death of neonate, IUFD; Infection; grade three and four laceration; history of allergy to herbal medicines used in ointment

Intervention groups
Partcipants, Mothers' entrance to the research will be done 4 hours after delivery with their consent. In control group, individuals will receive usual health recommendations according to the country's protocol and the ones in the Arnebia euchroma Ointment group will be provided with Arnebia euchroma Ointment Data collection will be performed by completing the questionnaire from the 4 hours after delivery.

Main outcome variables
Pain, wound healing.

General information

Reason for update

Acronym
بهبود و شدت درد زخم اپی زیاتومی

IRCT registration information
IRCT registration number: **IRCT20180110038302N2**
Registration date: **2018-04-29, 1397/02/09**
Registration timing: **registered_while_recruiting**

Last update: **2018-04-29, 1397/02/09**
Update count: **0**

Registration date
2018-04-29, 1397/02/09

Registrant information

Name
Mansoureh Yazdkhasti

Name of organization / entity
Alborz University medical science

Country
Iran (Islamic Republic of)

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+98 21 4401 8856

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-03-20, 1396/12/29

Expected recruitment end date
2018-08-22, 1397/05/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation the effect of mastic Arnebia euchroma Ointment resin on wound healing and perineal pain after childbirth in women had episiotomy in alborz in 1397

Public title

Evaluation the effect of mastic Arnebia euchroma Ointment resin on wound healing and perineal pain after childbirth in women had episiotomy in alborz in 1397

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

.Inclusion criteria: Healthy mothers (without anemia: HB>9g/dl : lack of systemic disease: not taking immunosuppressive drugs and corticosteroids: lack of acute or chronic disease such as diabetes: high blood pressure and kidney failure: lack of constipation and hemorrhoids: sickle cell: and cancer treatment (chemotherapy: radiotherapy) ...): avoiding the use of tobacco (cigarettes: hookahs: tobacco: naswar ...) and antibiotics during pregnancy: and gestational age: live fetus with head: spontaneous pain of labor without induction: no long-term rupture of water bag (more than 12 hours):

Exclusion criteria:

. Exclusion criteria: Evidence of infection (temperature higher than 38): Meconium-stained amniotic fluid: rupture grade 3 and 4: a history of sensitivity to mastic gum: varicosity and hemorrhoids: The women suffering from hematoma will be excluded: Moreove the women with a history of mental and personality illnesses: preterm labor: difficult delivery: abnormal infant: hospitalized infants: neonatal death

Age

From **14 years** old to **50 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **190**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomized

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Design, The study population consists of nulliparous women referred to the maternity hospital and had episiotomy in 2016 in karj

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Alborz University of Medical Science

Street address

Department of Nursing., Alborz University of Medical Science., Eshteraki St., Baghestan Blv

City

karj

Province

Alborz

Postal code

561-31452

Approval date

2018-03-09, 1396/12/18

Ethics committee reference number

1396.213´

Health conditions studied

1

Description of health condition studied

epizytomy

ICD-10 code

O90

ICD-10 code description

Complications of the puerperium, not elsewhere classified

Primary outcomes

1

Description

Pain

Timepoint

4 hours after intervention Days3،5،10

Method of measurement

rule Pain

Secondary outcomes

1

Description

Wound healing

Timepoint

4 hours after intervention Days3،5،10

Method of measurement

REEDA observation form

Intervention groups

1

Description

Control group: In control group, individuals will receive

usual health recommendations according to the country’s protocol.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kamali hospital

Full name of responsible person

Dr. Mansoureh Yazdkhshti

Street address

Karaj-Baghestan- Southern Common Blvd.-Alborz Nursing-Midwifery Faculty

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1829346253

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Mansoyazd@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Dr. Mansoureh Yazdkhshti

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Grant name

Grant code / Reference number

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

No

Title of funding source

Karaj University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

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

Karaj University of Medical Sciences

Full name of responsible person

Dr. Mansoureh Yazdkhshti

Position

Consultant

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Dr. Mansoureh Yazdkhshti

Position

استادیار

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Contact

Name of organization / entity
Karaj University of Medical Sciences

Full name of responsible person
Shokufe Torkashvand

Position
Instructor

Latest degree
Master

Other areas of specialty/work
Midwifery

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Email

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no program for its release

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
Not applicable