

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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

Participants, 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)

###### Phone

+98 21 4401 8856

###### Email address

m.yazdkhasti@abzums.ac.ir

##### 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  
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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**

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**Street address**

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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****Contact****Name of organization / entity**

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**Full name of responsible person**

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استاديار

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## Person responsible for updating data

shokufetorkashvand@gmail.com

### 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