

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Phytochemical investigations on myrtle and chamomlie essential oils and their effects on episiotomy: double blinded clinical trial

#### Protocol summary

##### Study aim

Phytochemical investigations on myrtle and chamomlie essential oils and their effects on episiotomy

##### Design

Randomized clinical trial with two intervention groups, parallel groups, double blind, 120 patients

##### Settings and conduct

The drug packages are similar and given to women by other person. This person does not inform about the package contents. This study is conducted in Fatemieh hospital of Hamadan city. Therefore, neither the researcher nor the women know the contents of the package and double blinding is performed.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Pregnancy age 37 weeks and higher at delivery time, maternal age 18-35 years, mediolateral incision and 2nd degree of episiotomy, not having physical diseases, not having pregnancy complications, not having condyloma or herpes lesions in the perineum  
Primigravida Exclusion Criteria: Infection during treatment, irregular use of the drug, refuse from continuing to participate in study

##### Intervention groups

Intervention groups: Chamomile Ointment will be prescribed twice in a day for ten days. This drug will be produced by Hamadan University of Medical Sciences. Myrtle Ointment will be prescribed twice in a day for ten days. This drug will be produced by Hamadan University of Medical Sciences. Placebo Ointment will be prescribed twice in a day for ten days. This drug will be produced by Hamadan University of Medical Sciences.

##### Main outcome variables

Wound healing; pain severity

#### General information

##### Reason for update

Adding of the placebo group

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20180707040370N7**

Registration date: **2020-06-15, 1399/03/26**

Registration timing: **prospective**

Last update: **2024-01-27, 1402/11/07**

Update count: **1**

#### Registration date

2020-06-15, 1399/03/26

#### Registrant information

##### Name

Ensiyeh Jenabi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 3838 0496

##### Email address

e.jenabi@umsha.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2020-06-21, 1399/04/01

#### Expected recruitment end date

2020-10-22, 1399/08/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Phytochemical investigations on myrtle and chamomlie essential oils and their effects on episiotomy: double blinded clinical trial

**Public title**

Phytochemical investigations on myrtle and chamomile essential oils and their effects on episiotomy

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Gestational age 37 weeks and higher at delivery time  
Maternal age 18-35 years  
Mediolateral incision and episiotomy degree 2  
No physical diseases  
No pregnancy complications  
No condyloma or herpes lesions in the perineum  
Primigravida

**Exclusion criteria:**

Infection during treatment  
Irregular use of the drug  
Refuse from continuing to participate in study

**Age**

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

**Gender**

Female

**Phase**

2

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **120**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The Excel computer program by ((Choose (randbetween(1;2;3) command, Randomly write the number 1 or 2 or 3 in front of each of these 120 people so that the people are evenly distributed. In this study, the number one in the group receiving chamomile, the number two in the group receiving Mort, and the number three in the group receiving placebo will be assigned.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The drug packages are similar and are given to women by other person. This person does not inform about the package contents. Therefore, neither the researcher nor the women knows the contents of the package and double blinding will be performed.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee**

**Name of ethics committee**

Ethics Committee of Hamadan University of Medical Sciences

**Street address**

Hamadan University of Medical Sciences, Fahmiheh Street, Hamadan

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838678

**Approval date**

2020-05-23, 1399/03/03

**Ethics committee reference number**

IR.UMSHA.REC.1399.217

**Health conditions studied****1****Description of health condition studied**

Episiotomy

**ICD-10 code**

O90.1

**ICD-10 code description**

Disruption of perineal obstetric wound

**Primary outcomes****1****Description**

Pain severity

**Timepoint**

Pre intervention, 6 hour and 5 and 10 days after intervention

**Method of measurement**

Visual analogue scale (VAS)

**2****Description**

Healing wound

**Timepoint**

Pre intervention, 6 hour and 5 and 10 days after intervention

**Method of measurement**

Episiotomy wound healing rate scale, REEDA (Redness, Edema, Ecchymosis, Discharge, Approximation)

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Chamomile Ointment will be prescribed twice in a day for ten days. This drug will be produced by Hamadan University of Medical Sciences.

**Category**

Treatment - Drugs

**2****Description**

Chamomile Ointment will be prescribed twice in a day for ten days. This drug will be produced by Hamadan University of Medical Sciences.

**Category**

Treatment - Drugs

**3****Description**

Control group: Placebo Ointment will be prescribed twice in a day for ten days. This drug will be produced by Hamadan University of Medical Sciences.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Fatemieh Hospital

**Full name of responsible person**

Ensiyeh Jenabi

**Street address**

Fatemieh Hospital, Pasdaran Ave.

**City**

Hamadan

**Province**

Hamadan

**Postal code**

987545433

**Phone**

+98 81 3827 8080

**Email**

Fatemieh.Hospital@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Saeid Bashirian

**Street address**

Vice-chancellor for Research, Hamadan University of Medical Sciences, Shahid Fahmideh Av

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0717

**Email**

S\_bashirian@yahoo.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Hamedan 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**

Hamedan University of Medical Sciences

**Full name of responsible person**

Ensiyeh Jenabi

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Vice-chancellor for Research, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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en.jenabi@yahoo.com

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

Hamedan University of Medical Sciences

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not 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**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

Not applicable

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

A portion of the information, such as information on the  
main outcome or the like, can be shared.

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

6 months after publishing the results

**To whom data/document is available**

Researchers working in academia

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

Data analysis is permitted with the author's permission.

**From where data/document is obtainable**

Hamadan University of Medical Sciences

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

6 months after of paper publish

**Comments**