

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0496

Email

en.jenabi@yahoo.com

Person responsible for scientific 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

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Ensiyeh Jenabi

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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