Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 chamomlie 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.
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987545433
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+98 81 3827 8080
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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
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6517838695
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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
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Vice-chancellor for Research, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
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Person responsible for updating data

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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