

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Study on phytochemistry and clinical effect of chamomile on hemorrhoid in lactating women

Protocol summary

Study aim

clinical effect of chamomile on hemorrhoid in lactating women

Design

Clinical trial with control group, with parallel groups, double blind, randomized

Settings and conduct

Participants are randomly assigned to the two groups of 35 recipients of Chamomile Ointment and placebo group. This study will be conducted in Comprehensive Health Centers of Hamadan city. In this study, neither the researcher nor the women knows the contents of the package and double blinded will be performed. In intervention group, Chamomile Ointment and in Control group, placebo will be prescribed Twice in a day along two weeks.

Participants/Inclusion and exclusion criteria

Criteria inclusion: Confirmation of diagnosis of grade 1 and 2 hemorrhoids; presence of hemorrhoid symptoms for 1 week; not using cigarette or alcohol; not having physical or mental diseases; not using Anti-hemorrhoid drugs
Criteria exclusion: Drug intolerance

Intervention groups

Chamomile oil will be prescribed in the form of Ointment , Twice in a day along two weeks. This drug Will be produced by Hamadan University of Medical Sciences.

Main outcome variables

Itching; pain severity; Hemorrhage

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180707040370N6**

Registration date: **2020-03-10, 1398/12/20**

Registration timing: **prospective**

Last update: **2020-03-10, 1398/12/20**

Update count: **0**

Registration date

2020-03-10, 1398/12/20

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

2020-04-08, 1399/01/20

Expected recruitment end date

2020-06-09, 1399/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study on phytochemistry and clinical effect of chamomile on hemorrhoid in lactating women

Public title

clinical effect of chamomile on hemorrhoid in lactating women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Confirmation of diagnosis of grade 1 and 2 hemorrhoids, symptoms of hemorrhoids for 1 week not using cigarette or alcohol not having physical or mental diseases not using anti-hemorrhoid drugs

Exclusion criteria:

Drug intolerance

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Randomized

Randomization description

Participants are randomly selected by (randbetween (1; 2)) command, in the Excel computer program that are assigned to the two groups of 35 recipients of Chamomile Ointment and placebo.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drug packages are similar and were given to menopausal 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

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

2020-03-07, 1398/12/17

Ethics committee reference number

IR.UMSHA.REC.1398.1079

Health conditions studied

1

Description of health condition studied

Hemorrhoid

ICD-10 code

K64

ICD-10 code description

Hemorrhoids and perianal venous thrombosis

Primary outcomes

1

Description

Itching

Timepoint

The first, seventh and fourteenth days

Method of measurement

Visual scale of hemorrhoids symptoms

2

Description

Pain severity

Timepoint

The first, seventh and fourteenth days

Method of measurement

Visual scale of hemorrhoids symptoms

3

Description

Hemorrhage

Timepoint

The first, seventh and fourteenth days

Method of measurement

Visual scale of hemorrhoids symptoms

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Chamomile Ointment will be prescribed in the form of Oral Capsule 500 mg, Twice in a day along two months. This drug Will be produced by Hamadan University of Medical Sciences.

Category

Treatment - Drugs

2

Description

Control group: placebo will be prescribed in the form of Eucerin based Twice in a day along two months. The placebo is made in Hamadan University of Medical Sciences.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive Health Service Center of Shohada

Full name of responsible person

Ensiyeh Jenabi

Street address

Comprehensive Health Service Center of Shohada., Takhti Ave., Hamadan

City

Hamadan

Province

Hamadan

Postal code

6517838344

Phone

+98 81 3252 4321

Email

Shohada.health@yahoo.com

2

Recruitment center

Name of recruitment center

Comprehensive Health Service Center of Khezr

Full name of responsible person

Ensiyeh Jenabi

Street address

Comprehensive Health Service Center of Khezr., Khezr Ave., Hamadan

City

Hamadan

Province

Hamadan

Postal code

6517838289

Phone

+98 81 3266 0550

Email

Khezr.Health@yahoo.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_bashrian@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

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en.jenabi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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