

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of Coconut oil ointment on the symptoms of Hemorrhoids in pregnant women

Protocol summary

Study aim

Determine the effect of Coconut oil ointment on Hemorrhoids symptoms in pregnant women

Design

Phase III parallel Clinical trial with Control group, No Blindness, Randomized allocation classified according to the gestational age , On 62 eligible pregnant women

Settings and conduct

The research units referring to Mashhad comprehensive health centers were selected using easy method and with randomized allocation classified according to the gestational age, they will be divided into intervention and control groups. Patients will be examined for symptoms in the 1, 7 and 14 days. If none of the symptoms of hemorrhoids recover within a week, they will be excluded from the study and will be referred to the specialist for further investigation, if recovery is observed in symptoms, treatment continues for another week, and if treatment is complete within one week, treatment will end

Participants/Inclusion and exclusion criteria

Reading and writing literacy, Women 15 to 45 years of age with Single-crowned pregnancy, Gestational age 14 to 36 weeks, having grade 1 or 2 Hemorrhoids, No history of colorectal cancer in person or their first degree relatives, Absence of systemic diseases obstetrics problems and other colorectal diseases, Absence of psychiatric problems and Occurrence an unpleasant incident in the last quarter, Non-use of Tobacco, Not having Depression Anxiety or severe Stress

Intervention groups

In Intervention group, in addition to giving advice on lifestyle modifications according to the country's guidelines, 50% coconut oil ointment with Vaseline base will be used as a full Applicator twice daily for 14 days. To the control group will give advice on lifestyle modifications according to the country's guidelines

Main outcome variables

The mean score of Hemorrhoid symptoms including Pain,

Bleeding, Itching and Prolapse

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181204041842N1**

Registration date: **2019-01-17, 1397/10/27**

Registration timing: **prospective**

Last update: **2019-01-17, 1397/10/27**

Update count: **0**

Registration date

2019-01-17, 1397/10/27

Registrant information

Name

Elahe Jesmani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3893 4278

Email address

jesmanie961@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-12, 1397/11/23

Expected recruitment end date

2019-09-14, 1398/06/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of Coconut oil ointment on the symptoms of Hemorrhoids in pregnant women

Public title
The effect of Coconut oil ointment on pregnancy Hemorrhoids

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Reading and writing literacy Pregnant women 15 to 45 years of age Gestational age 14 to 36 weeks Single-crowned pregnancy Confirmation of grade one or two Hemorrhoids diagnosis by female Doctor center and Researcher The presence of symptoms of Hemorrhoids for at least seven days
Exclusion criteria:
 Use of Anti-Hemorrhoid drugs at present History of Colorectal cancer in person or their first degree relatives Having other Colorectal diseases Having of Systemic diseases The presence of Obstetrics problems The presence of Psychiatric problems Occurrence of an unpleasant incident in the last quarter Use of Drugs or other smoking Having Depression, Anxiety or severe Stress

Age
From **15 years** old to **45 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **62**

Randomization (investigator's opinion)
Randomized

Randomization description
Individuals using Stratified Random allocation for gestational age, by Randomization site into two equal and identical groups for Gestational age (Intervention and Control) are Allocated

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics committee of Mashhad University of Medical Sciences
Street address
 Assistance of Research and Technology of Mashhad University of Medical Sciences, Qureishi building, Daneshgah avenue
City
 Mashhad
Province
 Razavi Khorasan
Postal code
 91388-13944
Approval date
 2018-11-13, 1397/08/22
Ethics committee reference number
 IR.MUMS.NURSE.REC.1397.064

Health conditions studied

1

Description of health condition studied
Hemorrhoids in pregnancy

ICD-10 code
O22.4

ICD-10 code description
Haemorrhoids in pregnancy

Primary outcomes

1

Description
Hemorrhoid pain score

Timepoint
The beginning of the intervention, 7th and 14th days after intervention

Method of measurement
Visual Analogue Scale of the Hemorrhoids symptoms

2

Description
Hemorrhoid bleeding score

Timepoint
The beginning of the intervention, 7th and 14th days after intervention

Method of measurement
Visual Analogue Scale of the Hemorrhoids symptoms

3

Description
Hemorrhoid itching score

Timepoint
The beginning of the intervention, 7th and 14th days after intervention

Method of measurement
Visual Analogue Scale of the Hemorrhoids symptoms

4

Description

Hemorrhoid prolapse score

Timepoint

The beginning of the intervention, 7th and 14th days after intervention

Method of measurement

Visual Analogue Scale of the Hemorrhoids symptoms

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition to giving advice on lifestyle modifications according to the country's guidelines, 50% coconut oil ointment with Vaseline base will be used as a full Applicator twice daily for 14 days

Category

Treatment - Drugs

2

Description

Control group: To the control group will give advice on lifestyle modifications according to the country's guidelines

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Health Center No. 1

Full name of responsible person

Dr. Naser Amini

Street address

Between Vakil Abad 66 and 68, Vakil Abad Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9179793945

Phone

+98 51 3501 5080

Email

AminiN1@mums.ac.ir

2

Recruitment center

Name of recruitment center

Mashhad Health Center No. 2

Full name of responsible person

Dr. Ali Asghar Mahmoudi

Street address

Near to Vahdat Park, Vahdat Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9153913153

Phone

+98 51 3365 1652

Email

MahmoudiAA1@mums.ac.ir

3

Recruitment center

Name of recruitment center

Mashhad Health Center No. 3

Full name of responsible person

Dr. Brat Ali Arabnejad

Street address

Payam St, Ershad 8, Khayyam Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9185837715

Phone

+98 51 3763 4007

Email

ArabnejadBA1@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Assistance of Research and Technology of Mashhad University of Medical Sciences, Qureishi building, Daneshgah avenue

City

Mashhad

Province

Razavi Khorasan

Postal code

91775-1365

Phone

+98 51 3882 3255

Email

Tafaghodim@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Elahe Jesmani

Position

Midwifery Master Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

School of Nursing and Midwifery, Ibn Sina Street,
Doktora Crossroad

City

Mashhad

Province

Razavi Khorasan

Postal code

91889-93684

Phone

+98 51 3893 4278

Fax**Email**

JesmaniE961@mums.ac.ir

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

Mashhad University of Medical Sciences

Full name of responsible person

Samira Ebrahimzadeh Zagami

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

Department of Midwifery, School of Nursing and
Midwifery, Ibn Sina Street, Doktora Crossroad

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Email

EbrahimzadehZS@mums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Elahe Jesmani

Position

Midwifery Master Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

School of Nursing and Midwifery, Ibn Sina Street,
Doktora Crossroad

City

Mashhad

Province

Razavi Khorasan

Postal code

91889-93684

Phone

+98 51 3893 4278

Fax**Email**

JesmaniE961@mums.ac.ir

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

Undecided - It is not yet known if there will be a plan to make this available

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

Undecided - It is not yet known if there will be a plan to make this available