

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 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**

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**Province**

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**Postal code**

91889-93684

**Phone**

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**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**

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**Province**

Razavi Khorasan

**Postal code**

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**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,  
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Mashhad

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**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