# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## Comparison of the effect of topical ointment Myrtus Communis and anti-hemorrhoid on first and second grade hemorrhoid symptoms and the quality of life of women in post delivery period: a triple-blind controlled clinical trial

## Protocol summary


**Summary**

The purpose of this clinical trial, with two parallel arms triple blind is to determine the effects of topical ointment Myrtus communis on symptoms of internal hemorrhoid grade one and two in Women in the post delivery period referred to the clinic of Khatam al-Anbia Hospital in tehran. After obtaining written informed consent qualified subject to a randomized block design,eligible people with four and six blocks allocation ratio of 1:1 would be allocated in two group. ointment (construction Khoraman pharmaceutical company, containing of Myrtus communis ) and ointment anti-hemorrhoid quite similar to ointment Myrtus communis (RECTOL) by a uninvolved person in the sampling and data collection will be placed in a sealed opaque envelope with consecutive numbers. Ointments are identified for women aged 18-40 years old who have at least 4 weeks and a maximum of 4 months since their delivery, either naturally or as a surgical procedure (such as Nullipar and Multipar) and their hemorrhoids with clinical signs and approval by the general surgeon. It will not be caused by systemic diseases. Persons will intake prescription ointmentes daily (every 12 hours). The mean score of the symptoms of hemorrhoid in the designated visits and quality of life as a primary consequences will be assessed and compared in two groups.


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT201612278170N10**
Registration date: **2017-08-07, 1396/05/16**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

**Registration date**

2017-08-07, 1396/05/16

**Registrant information**


**Name**

Jamileh Malakouti

**Name of organization / entity**

Nursing Faculty

**Country**

Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**


**Funding source**

Assistance of Research(Research and technology)Tabriz University of Medical Sciences


**Expected recruitment start date**

2017-06-22, 1396/04/01

**Expected recruitment end date**

2017-08-20, 1396/05/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effect of topical ointment Myrtus Communis and anti-hemorrhoid on first and second grade hemorrhoid symptoms and the quality of life of women in post delivery period: a triple-blind controlled

clinical trial

**Public title**
effects of topical ointment Myrtus communis on symptoms of internal hemorrhoid grade one and two
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
Inclusion criteria: Women have given birth for at least 4 weeks and up to 4 months from their delivery, either in the normal way of any cesarean section (including Nully Par and Multipar); women in post delivery period who have been diagnosed their hemorrhoids first and second degree with clinical symptoms and confirmed by the Surgeon General; women between 18-40 years; Women in the postpartum period whose hemorrhoids are not caused by systemic diseases such as hypertension; hemorrhoid symptomsfor at least more than 7 days; The ability to read and write. Exclusion criteria: Use of Systemic steroid Drugs and non-steroidal anti-inflammatory drugs and analgesics and anti-hemorrhoid treatments (for a one month prior to the study) and the use of anticoagulant drugs; require surgical procedure for the treatment of hemorrhoids (a gastroenterologist confirmed by clinical testing and colonoscopy); women with problems such as abscesses, anorectal, fistula, tuberculosis, herpes, varicella, fungal infection (confirmed by clinical trials or colonoscopy); risk of gastrointestinal tract infectious inflammatory diseases or colorectal cancer (as the patient); The previous use of laser or the use of medication felebotonic to treat hemorrhoids a week before the study (as the patient); Delivery with vacuums or forceps and delivery of cesarean section with large ancision; the company in another intervention study.
**Age**
From **18 years** old to **40 years** old
**Gender**
Female

**Phase**
2
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **54**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
**Blinding (investigator's opinion)**
Triple 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 Tabriz University of Medical Sciences
**Street address**
Vice Chancellor for Research and Technology University of Medical Sciences, Golgasht Street, Azadi Street
**City**
Tabriz
**Postal code**
**Approval date**
2017-05-08, 1396/02/18
**Ethics committee reference number**
IR.TBZMED.REC.1396.125

## Health conditions studied

### 1

**Description of health condition studied**
hemorrhoid
**ICD-10 code**
K62.9
**ICD-10 code description**
Disease of anus and rectum, unspecified

## Primary outcomes

### 1

**Description**
The mean score of the symptoms of hemorrhoids
**Timepoint**
Before intervention, 1, 2, 4 and 8 weeks after intervention
**Method of measurement**
(Colo-Rectal Evaluation of Clinical Therapeutics Scale) (CORECTS)

### 2

**Description**
Quality of life score
**Timepoint**
Before intervention، 4 and 8 weeks after intervention
**Method of measurement**
The World Health Organization Quality of Life questionnaire of 26 questions (WHOQOL-BREF)

## Secondary outcomes

### 1

**Description**
The frequency of side events incidence
**Timepoint**

During 8 weeks after intervention

**Method of measurement**

The side events check list

**2**

**Description**

The patients satisfaction of received drug

**Timepoint**

4 and 8 weeks after intervention

**Method of measurement**

The check list of satisfaction of received drug

## Intervention groups

**1**

**Description**

Intervention group: ointment Myrtus communis, topical, every 12 hours for 4 weeks

**Category**

Treatment - Drugs

**2**

**Description**

Control group: ointment anti-hemorrhoid, quite similar to ointment Myrtus communis, topical, every 12 hours for 4 weeks

**Category**

Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

The Clinic of Khatam al-Anbia Hospital

**Full name of responsible person**

Khadijeh Samady

**Street address**

Khatam al-Anbia Hospital, Rashid Yasemi Street, higer thanVanak, Valiasr Avenue

**City**

Tehran

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Vice President of Research Tabriz University Of Medical Sciences

**Full name of responsible person**

Samady khadijeh

**Street address**

Tabriz University Of Medical Science, Golgasht Street, Azadi Street, Tabriz

**City**

Tabriz

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice President of Research Tabriz University Of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Khadijeh Samady

**Position**

A graduate student in midwifery

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

University of Medical Sciences

**Full name of responsible person**

Malakouti.Jamileh

**Position**

Master of Midwifery

**Other areas of specialty/work**

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
*empty*
**Study Protocol**
*empty*
**Statistical Analysis Plan**
*empty*
**Informed Consent Form**
*empty*
**Clinical Study Report**
*empty*
**Analytic Code**
*empty*
**Data Dictionary**
*empty*