Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 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)
Phone
+98 41 1477 2699
Email address
malakoutij@tbzmed.ac.ir

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

Street address

School of Nursing and Midwifery, South Shariati Street, Tabriz

City

Tabriz

Postal code

Phone

+98 21 6559 0571

Fax

Email

samady.1375@gmail.com

Web page address

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

Street address

School of Nursing and Midwifery, South Shariati Street, Tabriz

City

Tabriz

Postal code

66156-15733

Phone

+98 41 3479 6770

Fax

Email

samady.1375@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Khadijeh Samady

Position

Student of Master in Midwifery

Other areas of specialty/work

Street address

Unit 2, Building Negin, East Paksan Street, Fardis, Karaj, Alborz

City

Karaj

Postal code

Phone

+98 26 3657 1873

Fax

Email

samady.1375@gmail.com

Web page address

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