

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison the effectiveness of the use of glyceryl three nitrate ointment and mefenamic acid on pain, headache, and gastrointestinal disorders in primary dysmenorrhea women aged 18 to 30 years old without delivery

Protocol summary

Summary

This is a single blind, single- center randomized clinical trial. The aim of this study is to compare the effect of glyceryl trinitrate ointment and mefenamic acid capsule on dysmenorrhea. Our sample size is 160 who are enrolled based on inclusion criteria. The patients are randomly divided into two groups. The first group uses 2.5 mg glyceryl trinitrate ointment for 4 hours on the abdomen skin and under navel for 2 days. In the second group, 250 mg mefenamic acid capsule is administered every 8 hours per day for 48 hours. Treatment continues for three cycles of menses. Then patients are asked to express their pain with a number from 0 to 10. The amount of dysmenorrhea is analyzed between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016121311020N9**
Registration date: **2017-01-10, 1395/10/21**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-01-10, 1395/10/21

Registrant information

Name

Maryam Khoshideh

Name of organization / entity

Tehran University of Medical Sciences, Arash Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 7788 0909

Email address

khooshide@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Zahedan University of Medical Science

Expected recruitment start date

2013-05-05, 1392/02/15

Expected recruitment end date

2016-02-01, 1394/11/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effectiveness of the use of glyceryl three nitrate ointment and mefenamic acid on pain, headache, and gastrointestinal disorders in primary dysmenorrhea women aged 18 to 30 years old without delivery

Public title

Effects of glyceryl three nitrate ointment and mefenamic acid capsule on treatment of dysmenorrhea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 18 to 30 years old, primary dysmenorrhea; BMI between 19 and 27; normal ultrasonography, no history of birth Exclusion criteria: Abnormal ultrasound, pelvic and cardiovascular disease, alcohol consumption, drug addiction

Age

From **18 years** old to **30 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran University of Medical Sciences , Deputy of Research

Street address

Qods St, Keshavarz Blvd

City

Tehran

Postal code**Approval date**

2008-01-23, 1386/11/03

Ethics committee reference number

1133

Health conditions studied**1****Description of health condition studied**

primary dysmenorrhea

ICD-10 code

N94.4

ICD-10 code description

Primary dysmenorrhoea

Primary outcomes**1****Description**

dysmenorrhea

Timepoint

every 4 hours up to 48 hours after treatment

Method of measurement

VAS

Secondary outcomes**1****Description**

headache

Timepoint

every 4 hours up 48 hours after treatment

Method of measurement

asking the patient

2**Description**

gastrointestinal disorder

Timepoint

every 4 hours up 48 hours after treatment

Method of measurement

asking the patient

Intervention groups**1****Description**

Intervention group: Patients use 2.5 mg glyceryl trinitrate ointment for 4 hours on the abdomen skin and under navel for 2 days in three cycles of their menses.

Category

Treatment - Drugs

2**Description**

Control group: Patients use 250 mg mefenamic acid capsules every 8 hours per day for 48 hours in their three cycles of menses.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ali Ebne Abitaleb Hospital

Full name of responsible person

Dr. Maryam Khooshide

Street address**City**

Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Zahedan University of Medical Science

Full name of responsible person

Dr. Mohammad Hashemi

Street address

Khlije Fars boulevard

City

Zahedan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Zahedan University of Medical Science

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**

Tehran University of Medical Science

Full name of responsible person

Dr. Maryam Khooshide

Position

gynecologist

Other areas of specialty/work**Street address**

Arash women hospital, Rashid street, Resalat highway, Tehranpars

City

Tehran

Postal code**Phone**

+98 21 7771 9922

Fax**Email**

khooshide@yahoo.com

Web page address

Person responsible for scientific

inquiries

Contact**Name of organization / entity**

Tehran University of Medical Science

Full name of responsible person

Dr. Maryam Khooshide

Position

gynecologist

Other areas of specialty/work**Street address**

Arash Womens Hospital, Rashid Avenue, Resalat Highway, Tehranparse

City

Tehran

Postal code**Phone**

+98 21 7771 9922

Fax**Email**

khooshide@yahoo.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity****Full name of responsible person****Position****Other areas of specialty/work****Street address****City****Postal code****Phone**

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Fax**Email**

khooshide@yahoo.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