Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Abitleb 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

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Arash women hospital, Rashid street, Resalat highway,Tehranpars

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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