

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The study of the effects of Melatonin and Meloxicam on sleep quality and pain severity in patients with primary dysmenorrhea

Protocol summary

Summary

The title of this research will be the study of the effects of melatonin and meloxicam on sleep quality and pain severity in patients with primary dysmenorrhea, The Objectives of this research will be the determine the most appropriate treatment to pain decrease and improve sleep quality in patients, The design of this research will be done based on clinical trial in this way that qualified women will be selected through of the questionnaire and careful clinical interview to the numbers of 42 people and they will be divided by the method of random numbers table to the 3 equal groups, Major Inclusion criteria: Women 18 to 35 years old and nulipar; Regular cycles 21 to 35 days; Normal BMI 19.8 to 25; Medicines and certain supplements and herbal medicines dont use before and during of the study, Exclusion criteria: Secondary dysmenorrhea from pelvic disorders; chronic diseases; Mental disorders; Lack of consent of the person to continue participating in the study, The treatment interventions will be by using of 2 group of drugs, melatonin 3 mg and meloxicam 7.5mg, once at night for 5 night in the menstrual cycles before intervention and during intervention and to control group is doing intervention in the same way with placebo. Main outcome measures variables consist of dysmenorrhea pain severity and sleep Quality that will be measured through McGill pain ruler and pitsburg questionnaire and the findings will be analyzed by Spss software

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015031521475N1**

Registration date: **2015-07-10, 1394/04/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-07-10, 1394/04/19

Registrant information

Name

Fariba Mahmoudzadeh

Name of organization / entity

kermanshah University Of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 84 3334 2021

Email address

f.mahmoudzadeh@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for reserch,Kermanshah University of Medical Science

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study of the effects of Melatonin and Meloxicam on sleep quality and pain severity in patients with primary dysmenorrhea

Public title

Primary Dysmenorrhea pain severity

Purpose

Treatment

Inclusion/Exclusion criteria
 Inclusion criteria: Women 18 to 35 years old and nulipar;
 Regular cycles 21 to 35 days; Normal BMI 19.8 to 25;
 Medicines and certain supplements and herbal medicines
 not used in before and during of the study, Exclusion
 criteria: Secondary dysmenorrhea from pelvic disorders;
 Chronic diseases; Mental disorders; Lack of person
 satisfaction in order to participating continue in the study

Age
 From **18 years** old to **35 years** old

Gender
 Female

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **42**

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Single blinded

Blinding description

Placebo
 Used

Assignment
 Parallel

Other design features
 The Volunteers will be selected through of the
 questionnaire and clinical interview to the numbers of 42
 people and they will be divided through table of random
 numbers (assigned 2 digits code and fingerings on the
 above table) to the 3 groups equal

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Of Kermanshah University Of
 Medical Sciences

Street address

Beheshti Street

City

Kermanshah

Postal code

6715847141

Approval date

2015-05-26, 1394/03/05

Ethics committee reference number

kums.rec.1394.22

Health conditions studied

1

Description of health condition studied

Primary Dysmenorreh

ICD-10 code

N94-4

ICD-10 code description

Pain and other conditions associated with female genital
 organs and menstrual cycle

Primary outcomes

1

Description

Dysmenorreh Pain Severity

Timepoint

The menstrual cycle before intervention and during
 intervention for 5 night

Method of measurement

According to the Mac Gill pain scale ruler

2

Description

Quality Of Sleep

Timepoint

The menstrual cycle before intervention and during
 intervention for 5 night

Method of measurement

According to the results Acti graphic

Secondary outcomes

1

Description

BMI

Timepoint

The menstrual cycle before intervention and during
 intervention for 5 night

Method of measurement

The result of dividing weight on the square of height

2

Description

Bed Time

Timepoint

The menstrual cycle before intervention and during
 intervention for 5 night

Method of measurement

According to the results Acti graphic

3

Description

The Duration Of Sleep

Timepoint

The menstrual cycle before intervention and during
 intervention for 5 night

Method of measurement

According to the results Acti graphic

4

Description

Waking At Night

Timepoint

The menstrual cycle before intervention and during intervention for 5 night

Method of measurement

According to the results Acti graphic

Intervention groups

1

Description

Control group : Folic Acid 10 mg with Folate brand name of pharmaceutical manufacturer Mehr, Once at night for 5 night in the menstrual cycles before intervention and time intervention

Category

Placebo

2

Description

Intervention group 1 : Melatonin 3 mg of pharmaceutical manufacturer seppid drug, Once at night for 5 night in the menstrual cycles before intervention and time intervention, Chemical combination acetyl 5 methoxy triptamine

Category

Treatment - Drugs

3

Description

Intervention group 2 : Meloxicam 7.5 mg of Manufacturer compani Loghman with mubik brand name, Once at night for 5 night, in the menstrual cycles before intervention and time intervention

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bustan Dormitory, Kermanshah University of Medical Sciences

Full name of responsible person

Dr Fariba Mahmoudzadeh, Assistant Professor of Obstetrics and Gynecology

Street address

Zekaria Razi Street, Rudaki Street

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for reserch of Kermanshah University Of Medical Sciences

Full name of responsible person

Dr Farid Najafi

Street address

No 2, Beheshti Street

City

Kermanshah

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice chancellor for reserch of Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Dr Farahnaz Keshavarzi

Position

Associate member of the faculty of the department of Obstetrics and Gynecology Kermanshah, Fellowship

Other areas of specialty/work

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr Fariba Mahmoudzadeh

Position

Assistant Professor of Obstetrics and Gynecology

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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

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr Farahnaz Keshavarzi

Position