

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the effect of nano-Curcumin with Curcumin and control group on primary dysmenorrhea among 18-27 years old women

Protocol summary

Study aim

Studying and comparing the effectiveness of nano-curcumin to curcumin in the pain of primary dysmenorrhea

Design

A placebo controlled, parallel group, double blind, in three randomised controlled groups, phase 3 clinical trial

Settings and conduct

In this double blind experiment, qualified models will be chosen by questionnaire at the universities and Shohadaye Tajrish Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: having primary dysmenorrhea age of 18-27 Informed consent Exclusion criteria: pregnancy and lactation hypersensitivity to the Curcumin products using other drugs asthma, GI tract diseases, cholelithiasis and obstruction of gall duct intolerance of NSAIDs using anti-coagulant agents developing ovarian cysts using OCPs

Intervention groups

Patients enter in 3 groups which two of them will be treatment group and the other group will be a control group. All three groups will receive mefenamic acid for the control of menstrual pain. Control group will receive mefenamic acid and placebo for three consecutive menstrual periods. Nano-curcumin group will receive mefenamic acid and nano-curcumin for three consecutive menstrual periods. Curcumin group will receive mefenamic acid and curcumin for three consecutive menstrual periods.

Main outcome variables

Pain severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160813029327N11**

Registration date: **2018-05-27, 1397/03/06**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-27, 1397/03/06**

Update count: **0**

Registration date

2018-05-27, 1397/03/06

Registrant information

Name

Ramin Abrishami

Name of organization / entity

Islamic Azad University, Pharmaceutical sciences branch

Country

Iran (Islamic Republic of)

Phone

+98 21 2264 1889

Email address

r_abrishami@iaups.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-15, 1397/01/26

Expected recruitment end date

2018-09-17, 1397/06/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of nano-Curcumin with Curcumin and control group on primary dysmenorrhea among 18-27 years old women

Public title

Studying the effect of Nano-curcumin and curcumoup in primary dysmenorrhea

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

having primary dysmenorrhea age of 18-27 Informed consent

Exclusion criteria:

pregnancy and lactation hypersensitivity to the Curcumin products using other drugs asthma, GI tract diseases, cholelithiasis and obstruction of gull duct intolerance of NSAIDs using anti-coagulant agents developing ovarian cysts using OCPs

Age

From **18 years** old to **27 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **180**

Randomization (investigator's opinion)

Randomized

Randomization description

Random number table: based on Random Sequence Generator via random.org website three groups were made. Patients were allocated in one of three groups based on their entry sequence.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double blind study in which both researcher and patients don't know that which drug the patient have been used. Drugs will be dispensed by a third person in uniform packages with codes. Instructions on the number of consumption will not be seen by the prescriber.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Islamic Azad University of Tehran
Medical Science

Street address

Shariati Ave, Yakhchal Street, Tehran.

City

Tehran

Province

Tehran

Postal code

1941933111

Approval date

2017-08-27, 1396/06/05

Ethics committee reference number

IR.IAU.PS.REC.1396.143

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

Dysenorrhea

ICD-10 code

N94.4

ICD-10 code description

Primary dysmenorrhoea

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

Intensity of pain in primary dysmenorrhea

Timepoint

The measurement of intensity of pain, in first 3 days of 4 consecutive menstrual period

Method of measurement

Visual Analogue Scale and quality of life questionnaire

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

Quantity of Mefenamic acid

Timepoint

Patients in first month will just use Mefenamic acid and in three following months will use mefenamic acid besides study drugs if it is necessary.

Method of measurement

By questionnaire.

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

Intervention group 1: first intervention group is nano-curcumin group. This medicine in the form of 80 mg soft gelatin capsule will be consumed once daily by oral route for the first three days of menstruation for 3 consecutive months. Nano-Exir Sina is the manufacturer of this drug.

Category

Treatment - Drugs

2

Description

Control group: patients in this group will receive one 80 mg of placebo capsule daily by oral route for the first three days of menstruation for 3 consecutive months.

Category

Placebo

3

Description

Intervention group: Group 2 receives curcumin 500 mg tablets, tablets are manufactured by Dineh, Tehran, Iran. Tablets will be consumed twice daily by oral route for the first three days of menstruation for 3 consecutive months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Tajrish Hospital, Islamic Azad university of Medical Science

Full name of responsible person

Ramin Abrishami

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Shariati Ave, Yakhchal Street, Tehran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Yalda Ahmadnia

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Yaldae.am.nia@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

1

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Ramin Abrishami

Position

associated professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Full name of responsible person

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Position

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Latest degree

Specialist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Unidentified demographic and variables will be shared.

When the data will become available and for how long

After publication upto three years

To whom data/document is available

Academics

Under which criteria data/document could be used

Academic and/or clinical use

From where data/document is obtainable

via email to corresponding author

What processes are involved for a request to access data/document

after assurance about academic background

Comments

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Ramin Abrishami

Position

Ramin Abrishami

Latest degree

Specialist

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