

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Effect of aerobic exercise and consumption of curcumin on physiological parameters and edema in 18-35 years old women with premenstrual syndrome

Protocol summary

Summary

The purpose of this study is to investigate the effect of aerobic exercise and consumption of curcumin on physiological parameters of premenstrual syndrome in young non athletes women. For this purpose ,44 women with moderate to severe premenstrual syndrome selected and randomly assigned to 4 groups of 11 subject: aerobic training, curcumin, curcumin + aerobic training and control group. The instrument was Dickerson questionnaire (to diagnose premenstrual syndrome) and a questionnaire containing demographic and social information of samples. exercise Group did aerobic exercise for 12 weeks (3 times a week for 1 gour) with 50 to 60% of maximum heart rate .curcumin group used 100mg curcumin twice a day for 3 months(A week before menstruation till 3 days after onset of bleeding). Combined group did both of these interventions at the same time and the control group as well as the curcumin group used 100mg corn starch twice a day as placebo that have the same color as the main drug for 3 months(A week before menstruation till 3 days after onset of bleeding). In this study, curcumin supplements and corn powder (placebo) capsules were placed in the same shape and size capsules . The capsules was labeled 1 and 2 and gave to subjects by study investigator. Researcher and the subjects were unaware from the content of capsules. After analyzing the data, capsules contents will Inquiry from pharmacist. Data will be analyzed by using descriptive and inferential statistics at the significant level 0/05.

General information

Acronym

PMS

IRCT registration information

IRCT registration number: **IRCT2017010331745N1**

Registration date: **2017-04-22, 1396/02/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-04-22, 1396/02/02

Registrant information

Name

Ladan Zoodfekr

Name of organization / entity

Islamic Azad University Central Tehran Branch

Country

Iran (Islamic Republic of)

Phone

+98 21 8807 4870

Email address

ladanzoodfekr@gmail.com

Recruitment status

Recruitment complete

Funding source

In this study, the researcher does not have any funds

Expected recruitment start date

2016-06-04, 1395/03/15

Expected recruitment end date

2016-08-20, 1395/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of aerobic exercise and consumption of curcumin on physiological parameters and edema in 18-35 years

Public title

Effect of aerobic exercise and consumption of curcumin on Premenstrual syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 18-35 year old; Having regular menstrual cycles (28-35 days); Suffering from moderate or severe PMS and at least have five physical symptoms based on Dickerson questionnaire; Do not Consumption effective drugs (chemical or herbal) on the premenstrual syndrome in the recent quarter. Exclusion criteria: physical and mental illnesses like diabetes, biliary or kidney disease, epilepsy, thyroid disease or other metabolic disorders; Consumption hormonal, anti convulsants and anti depression drugs; Smoking and drug abuse.

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: **44**

Randomization (investigator's opinion)

Randomized

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

Single blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Sport Sciences Research Institute of Iran

Street address

No 3, 5th Dead End, Miremad St, Motahhari St, Tehran, Tehran Province

City

Tehran

Postal code**Approval date**

2016-05-21, 1395/03/01

Ethics committee reference number**Health conditions studied****1****Description of health condition studied**

premenstrual syndrome

ICD-10 code

N94.3

ICD-10 code description

Premenstrual tension syndrome

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

physical Indicators of Premenstrual syndrome

Timepoint

before intervention and 3 months after intervention

Method of measurement

Dickerson standard questionnaire , blood Measurements

2**Description**

emotional Indicators of Premenstrual syndrome

Timepoint

before intervention and 3 months after intervention

Method of measurement

Dickerson standard questionnaire , blood Measurements

3**Description**

psychological Indicators of Premenstrual syndrome

Timepoint

before intervention and 3 months after intervention

Method of measurement

Dickerson standard questionnaire , blood Measurements

4**Description**

prostaglandin E2

Timepoint

before intervention and 3 months after intervention

Method of measurement

Dickerson standard questionnaire , blood Measurements

5**Description**

estrogen

Timepoint

before intervention and 3 months after intervention

Method of measurement

Dickerson standard questionnaire , blood Measurements

6

Description

Progesteron

Timepoint

before intervention and 3 months after intervention

Method of measurement

Dickerson standard questionnaire , blood Measurements

7

Description

Prolactin

Timepoint

before intervention and 3 months after intervention

Method of measurement

Dickerson standard questionnaire , blood Measurements

8

Description

Blood suger

Timepoint

before intervention and 3 months after intervention

Method of measurement

Dickerson standard questionnaire , blood Measurements

9

Description

Edema

Timepoint

before intervention and 3 months after intervention

Method of measurement

Dickerson standard questionnaire , blood Measurements

Secondary outcomes

1

Description

physical Indicators of Premenstrual syndrome

Timepoint

before intervention and 3 months after intervention

Method of measurement

Dickerson standard questionnaire , blood Measurements

2

Description

emotional Indicators of Premenstrual syndrome

Timepoint

before intervention and 3 months after intervention

Method of measurement

Dickerson standard questionnaire , blood Measurements

3

Description

prolactin

Timepoint

before intervention and 3 months after intervention

Method of measurement

Dickerson standard questionnaire , blood Measurements

4

Description

progesteron

Timepoint

before intervention and 3 months after intervention

Method of measurement

Dickerson standard questionnaire , blood Measurements

5

Description

psychological Indicators of Premenstrual syndrome

Timepoint

before intervention and 3 months after intervention

Method of measurement

Dickerson standard questionnaire , blood Measurements

6

Description

blood suger

Timepoint

before intervention and 3 months after intervention

Method of measurement

Dickerson standard questionnaire , blood Measurements

7

Description

esterogen

Timepoint

before intervention and 3 months after intervention

Method of measurement

Dickerson standard questionnaire , blood Measurements

8

Description

prostaglandin E2

Timepoint

before intervention and 3 months after intervention

Method of measurement

Dickerson standard questionnaire , blood Measurements

9

Description

Edema

Timepoint

before intervention and 3 months after intervention

Method of measurement

Dickerson standard questionnaire , blood Measurements

Intervention groups

1

Description

curcumin 100 mg oral capsules, twice a day (from a week before mense till 3 days after bleeding)for 3

months + aerobic exercise with 50-60 % maximum heart rate, 3 times a week, 1 hour each day, for 3 months

Category

Treatment - Drugs

2

Description

curcumin 100 mg oral capsules twice a day(from a week before mense till 3 days after bleeding) for 3 months

Category

Treatment - Drugs

3

Description

Corn starch 100 mg oral capsules twice a day(from a week before mense till 3 days after bleeding) for 3 months

Category

Placebo

4

Description

Do aerobic exercise with 50-60 % maximum heart rate, 3 times a week, 1 hour daily, for 3 months

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Alzahra hospital, East Azarbayjan province

Full name of responsible person

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Islamic Azad University Central Tehran Branch

Full name of responsible person

Ali Niyazi

Street address

Forsate shirazi St, North Eskandari St, Azadi St, Tehran

City

Tehran

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 of Islamic Azad University Central Tehran Branch

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

Islamic Azad University

Full name of responsible person

Ladan Zoodfekr

Position

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Other areas of specialty/work

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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