

# 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**

PHD student

**Other areas of specialty/work**

**Street address**

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## Person responsible for updating data

### Contact

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**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*