Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of an aerobic training course with and without cumin supplementation on serum β-endorphin levels and pain intensity in non-athlete girls with primary dysmenorrhea

Protocol summary

Study aim

Enquiry into changes in serum β-endorphin levels and pain intensity in primary dysmenorrhea following aerobic training with or without cumin supplementation in non-athlete girls

Design

A total of 26 female students who were eligible according to inclusion criteria were selected by convenience sampling method and were assigned into the intervention or control groups via simple allocation method.

Settings and conduct

Participants were incorporated from students residing in student dormitories at Birjand State University. The study is single-blinded such that the participants were unaware of what capsules they consumed and into which group they were assigned. At the start of menstruation, the intervention group consumed cumin capsules on the first 3 days (300 milligrams every 8 hours), while the controls received placebo capsules (with the same dosage). On the third day, beta-endorphin serum levels were measured for all participants. Subsequently, the groups stopped consuming capsules and both took aerobic training from the 4th day of menstruation for 4 weeks. At the onset of the next menstruation, the exercise training stopped and serum levels of beta-endorphin were measured on the third day.

Participants/Inclusion and exclusion criteria

Main inclusion criteria: female students; moderate to severe primary dysmenorrhea. Main exclusion criterion: consumption of hormonal or analgesic medications before menstruation.

Intervention groups

Intervention Group (Cumin): At the start of menstruation, the intervention group members consumed cumin capsules (300 milligrams every 8 hours) on the first 3 days. On the third day, their beta-endorphin levels were measured. Subsequently, they stopped consuming capsules and took aerobic training from the 4th day of menstruation for 4 weeks. At the onset of the next menstruation, the exercise training stopped. Beta-endorphin levels were again measured on the third day. Control Group (Placebo): At the start of menstruation, the control group members consumed placebo capsules (300 milligrams every 8 hours) on the first 3 days. On the third day, their beta-endorphin levels were measured. Subsequently, they stopped consuming capsules and took aerobic training from the 4th day of menstruation for 4 weeks. At the onset of the next menstruation, the exercise training stopped. Beta-endorphin levels were again measured on the third day.

Main outcome variables

Serum levels of beta-endorphin; Pain intensity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140519017756N41**
Registration date: **2018-03-23, 1397/01/03**
Registration timing: **retrospective**

Last update: **2018-03-23, 1397/01/03**
Update count: **0**

Registration date

2018-03-23, 1397/01/03

Registrant information

Name

Mohammad Bagher Roozgar

Name of organization / entity

Birjand University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 56 3239 5680

Email address

mbroozgar@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-05-05, 1396/02/15

Expected recruitment end date

2017-07-22, 1396/04/31

Actual recruitment start date

2017-06-10, 1396/03/20

Actual recruitment end date

2017-07-11, 1396/04/20

Trial completion date

empty

Scientific title

The effect of an aerobic training course with and without cumin supplementation on serum β-endorphin levels and pain intensity in non-athlete girls with primary dysmenorrhea

Public title

Effects of aerobic training with cumin supplementation on serum β-endorphin levels and pain intensity

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age 18 to 25 years Moderate to severe dysmenorrhea (pain intensity score from 4 to 10) Single girl Non-athlete Regular monthly cycles of more than 21 days and less than 35 days Pain during menstruation

Exclusion criteria:

Consumption of hormonal medications and any type of herbal or chemical tranquilizers affecting menstrual bleeding since 48 hours before menstruation to the end of the research project Cardiovascular, hepatic and renal disease Genital tract infection Pelvic damage Secondary dysmenorrhea

Age

From **18 years** old to **25 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **26**

Actual sample size reached: **26**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants were assigned into study groups via simple allocation method.

Blinding (investigator's opinion)

Single blinded

Blinding description

The study is single-blinded such that the participants were unaware of what capsules they consumed and into which group they were assigned.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Birjand University of Medical Sciences

Street address

Ghaffari Ave.

City

Birjand

Province

South Khorasan

Postal code

9717853577

Approval date

2017-06-07, 1396/03/17

Ethics committee reference number

Ir.Bums.REC.1396.67

Health conditions studied

1

Description of health condition studied

Primary dysmenorrhoea

ICD-10 code

N94.4

ICD-10 code description

Primary dysmenorrhea

Primary outcomes

1

Description

Serum levels of beta-endorphin

Timepoint

on the third days of the first and next menstruation cycles

Method of measurement

ELISA kit (EASTBIOPHARM Company)

2

Description

Pain intensity

Timepoint
on the third days of the first and next menstruations
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group (Cumin): cumin capsules (300 milligrams every 8 hours) on the first 3 days plus 28 days of aerobic exercise from the fourth day
Category
Treatment - Other

2

Description
Control group (placebo): starch capsules (300 milligrams every 8 hours) on the first 3 days plus 28 days of aerobic exercise from the fourth day
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Girl dormitories of Birjand State University
Full name of responsible person
Mohadeseh Eidy Kakhky
Street address
Shokatabad Ave.
City
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South Khorasan
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615/97175
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Dr Tooba Kazemi
Street address
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drtooba.kazemi@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Birjand University of Medical Sciences
Proportion provided by this source
100
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
Birjand University of Medical Sciences
Full name of responsible person
Mohadese Eidy Kakhky
Position
Master student in training in Sport Physiology
Latest degree
Master
Other areas of specialty/work
Physiology
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person

Dr Nahid Ghanbarzadeh

Position
Gynecologist

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for updating data

Contact

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Birjand University of Medical Sciences

Full name of responsible person
Mohammad Bagher Roozgar

Position
Translator

Latest degree
Master

Other areas of specialty/work
Others

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
The research team intends to report the findings; however, we do not have a plan to share the raw data.

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
Study Protocol

When the data will become available and for how long
The protocol will be detailed in a paper that is being published. The paper will be available on the journal's website.

To whom data/document is available
To all researchers

Under which criteria data/document could be used
No certain criterion

From where data/document is obtainable
the journal's website

What processes are involved for a request to access data/document
The journal is open access.

Comments