

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

The effect of beta-caryophyllin supplementation on neuropeptides affecting brain reward axis, mental health, eating behaviour, appetite and body composition in obese women with food addiction

Protocol summary

Study aim

Determining the effect of beta-caryophyllin supplementation on neuropeptides affecting brain reward axis, mental health, eating behavior, appetite and body composition in obese women with food addiction

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 84 patients. Excel software rand function was used for randomization.

Settings and conduct

First, by installing announcements, people at the community will be invited to participate in the study. Then, the subjects will be divided to 3 groups in which obese women with food addiction (first group = 28 people) and obese women without food addiction (second group = 28 people) will be treated with beta-caryophyllin at a dose of 100 mg per day for 2 months. The third group (28 people) includes obese women with food addiction who will receive a placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Obese women with body mass index between 30 to 99.99 kg/m², confirmation of food addiction using the relevant questionnaire, being in the age range of 18-50 years Exclusion criteria: Reluctance to continue collaborating with the study, having a weight loss diet in the last two months, pregnancy and lactation, menopause, continuous use (more than once a week) of vitamin and mineral supplements in the past month, consumption of alcohol, cigarettes (more than 3 cigarettes per day for the past 6 months), tobacco or drugs, use of weight loss and appetite suppressants, physical activity started from more than last three weeks, history of neurological diseases or use of psychiatric drugs

Intervention groups

Obese women with food addiction (first group = 28

people), obese women without food addiction (second group = 28 people), The third group (28 people) includes obese women with food addiction who will receive a placebo.

Main outcome variables

Eating behavior

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200914048712N1**

Registration date: **2020-09-15, 1399/06/25**

Registration timing: **prospective**

Last update: **2020-09-15, 1399/06/25**

Update count: **0**

Registration date

2020-09-15, 1399/06/25

Registrant information

Name

shahab alizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8889 6696

Email address

sh_alizadeh@alumnus.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-07-23, 1400/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of beta-caryophyllin supplementation on neuropeptides affecting brain reward axis, mental health, eating behaviour, appetite and body composition in obese women with food addiction

Public title

The effect of beta-caryophyllin on food addiction of women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Body mass index between 30 to 99.99 kg/m²
confirmation of food addiction using the relevant questionnaire being in the age range of 18-50 years

Exclusion criteria:

Reluctance to continue collaborating with the study
Having a weight loss diet in the last two months
Menopause Continuous use (more than once a week) of vitamin and mineral supplements in the past month
Pregnancy and lactation Consumption of alcohol, cigarettes (more than 3 cigarettes per day for the past 6 months), tobacco or drugs Use of weight loss and appetite suppressants Physical activity started from more than last three weeks History of neurological diseases or use of psychiatric drugs

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

To apply randomization, the random blocks method with 4 blocks will be used. According to the sample size of 86 people, 22 blocks of 4 will be produced using the online site (www.sealedenvelope.com). In order to apply concealment in the randomization process, unique codes will be used on the medicine boxes, and the desired code will also be generated by the software. Participants will be entered into the study based on the sequence produced, and medication packages with a registered code will be assigned to the individual. Therefore, before selecting participants, the person will be unaware of the type of treatment she will receive, and also the random

sequence generated during the study will be unpredictable.

Blinding (investigator's opinion)

Double blinded

Blinding description

Since this study is a double-blind type, in order to conduct this research in a double-blind manner, at the beginning of the study, the cans containing the relevant capsules are coded in A and B by someone other than the researcher, so that the researcher and participants do not know the type of capsules received.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Tehran, Keshavarz Boulevard, Tehran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2020-09-10, 1399/06/20

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.443

Health conditions studied

1

Description of health condition studied

food addiction

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes

1

Description

Food addiction

Timepoint

at the baseline and end of study

Method of measurement

Yale Food Addiction Scale (YFAS)

Secondary outcomes

1

Description

Plasma oxytocin

Timepoint

Before and after the study

Method of measurement

ELISA

2

Description

plasma neuropeptide Y

Timepoint

Before and after the study

Method of measurement

ELISA

3

Description

Orexin

Timepoint

Before and after the study

Method of measurement

ELISA

4

Description

mental health

Timepoint

Beginning and end of the study

Method of measurement

Stress-Anxiety-Depression Questionnaire (DASS-21)

5

Description

Body composition

Timepoint

At the beginning and end of the study

Method of measurement

body composition analyzer

6

Description

Appetite

Timepoint

At the beginning and end of the study

Method of measurement

Appetite questionnaire

Intervention groups

1

Description

Intervention group: Intervention with a dose of 100 mg soft gel beta-caryophylline per day for 2 months, 1 orally daily. The manufacturer is still unknown.

Category

Treatment - Drugs

2

Description

Control group: placebo at a dose of 100 mg per day soft gel containing starch for 2 months every day 1 soft gel. The manufacturer is still unknown.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Community through notification

Full name of responsible person

Shahab Alizadeh

Street address

Keshavarz Boulevard, Tehran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1417613151

Phone

+98 21 8889 6696

Email

sh_alizadeh@alumnus.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Hassan Javanbakht

Street address

Keshavarz boulevard, Tehran university of medical sciences

City

Tehran

Province

Tehran

Postal code

1417613151

Phone

+98 21 8889 6696

Email

mhjavan2001@yahoo.com

Grant name

Vice Chancellor for Research, Tehran University of Medical Sciences

Grant code / Reference number**Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Hassan Javanbakht

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

keshavarz boulevard, Tehran university of medical sciences

City

Tehran

Province

Tehran

Postal code

1417613151

Phone

+98 21 4293 3333

Email

mhjavan2001@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Hassan Javanbakht

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

keshavarz boulevard, Tehran university of medical sciences

City

Tehran

Province

Tehran

Postal code

1417613151

Phone

+98 21 8889 6696

Email

mhjavan2001@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Hassan Javanbakht

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

keshavarz boulevard

City

Tehran

Province

Tehran

Postal code

1417613151

Phone

+98 21 8889 6696

Email

mhjavan2001@yahoo.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All data is shareable

When the data will become available and for how long

Access period starts from 1401

To whom data/document is available

Researchers working in academia and people in industry can also apply for the data.

Under which criteria data/document could be used

For research and industrial applications whose ultimate goal is health promotion

From where data/document is obtainable

Mohammad Hassan Javanbakht tell: 00989123640104

mhjavan2001@yahoo.com

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

By email and communication with the project manager

Comments