

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effects of nano-curcumin supplementation on leptin, adiponectin gene expression and serum levels of some adipokines in obese and overweight patients with migraine.

Protocol summary

Study aim

Determining the complementary effect of nanocurcumin on the expression of leptin gene, adiponectin and serum levels of some adipokines in obese and overweight patients with migraine

Design

Clinical trial study with control group, placebo, double blind, stratified-randomization, phase 3, on 44 patients.

Settings and conduct

The place of study is the Neurology Clinic of Imam Khomeini Hospital in Tehran. Forms and questionnaires will be completed according to the study method. At the beginning and end of the study (between headache attacks), blood sampling are performed, then the expression of the desired adipokines gene (Real-Time PCR method) and the desired serum factors (ELISA method) of the study are measured. Patients will be taught the necessary training at the beginning of study. The collected data are transferred to the SPSS software for analysis.

Participants/Inclusion and exclusion criteria

inclusion criteria include age 20 to 50 years, body mass index 25 to 35, episodic migraine without it, and voluntary patient collaboration. exclusion criteria: use of dietary supplements before the intervention, following special diets or special and intense physical activities, Having a comorbid condition, pregnancy, lactation and menopause, alcohol consumption, smoking

Intervention groups

The study groups included the nanocurcumin supplementation group and the control group (placebo-receiving group). Each nanocurcumin soft capsule contains 80 mg of nanocurcumin, which is taken once a day after breakfast. The placebo capsule contains oral paraffin, which is similar in appearance to the nanocurcumin soft gel capsule and is used in the same way.

Main outcome variables

Leptin and adiponectin gene expression, serum levels of leptin, adiponectin, resistin, bisfatin, MCP-1 levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160626028637N2**

Registration date: **2020-07-10, 1399/04/20**

Registration timing: **prospective**

Last update: **2020-07-10, 1399/04/20**

Update count: **0**

Registration date

2020-07-10, 1399/04/20

Registrant information

Name

Mohsen Sedighiyan

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2021-03-20, 1399/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of nano-curcumin supplementation on leptin, adiponectin gene expression and serum levels of some adipokines in obese and overweight patients with migraine.

Public title

The effect of turmeric-derived nanocurcumin supplementation on the amount of inflammation caused by adipose tissue in obese and overweight patients with migraine

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age = 20 to 50 (y) $25 \leq$ Body Mass Index (kg/m²) $\leq$ 35
Diagnosis of episodic migraine without aura, according to IHS criteria by neurologist
Voluntary cooperation of patients

Exclusion criteria:

use of dietary, vitamins and antioxidant supplements (such as curcumin) at least 4-6 weeks before the intervention
Following special diets or special and intense physical activity at the last 3 months before the intervention
Having comorbidity such as kidney disease, liver disease, pancreatitis, diabetes, cancer, thyroid disorders and inflammatory diseases, as well as patients with a history of heart attacks and strokes based on patient statements and medical history
Pregnancy, lactation and menopause
Alcohol consumption, cigarette smoking (at least 5 butts a day for the past 6 months), hookah, other types of tobacco and electronic types (VIP, anti-system)

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Stratified-Randomization method will be used in sampling to control sex and BMI variables. BMI will be considered as overweight (25-29/9) and obese (30 to 34.9) and sex will be considered as male and female, thus four lists including overweight female, obese female, overweight male and obese men will be considered. Then, patients will be divided equally into 2

groups by Permuted Block Randomization. Thus, randomly and using random table of numbers, 10 blocks of 2 consisting of different states (AB, BA, etc.) will be placed in each list and the order of treatment will be determined. Study groups are: nanocurcumin supplement group and the control group (group receiving placebo).

Blinding (investigator's opinion)

Double blinded

Blinding description

Supplements are coded by a third person and given to participants in a same form package. None of the participants and researchers are aware of the allocation of groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of School of Medicine- Tehran University of Medical Sciences

Street address

Central building of Tehran University of medical Sciences. Blv. Keshavarz

City

Tehran

Province

Tehran

Postal code

1417653911

Approval date

2020-06-30, 1399/04/10

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.190

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

Migraine

ICD-10 code

G43.0

ICD-10 code description

Migraine without aura

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

Leptin gene expression rate (percentage)
Timepoint
The beginning and end of the study
Method of measurement
Real-Time Polymerase chain reaction method

2

Description
Adiponectin gene expression rate (percentage)
Timepoint
The beginning and end of the study
Method of measurement
Real-Time Polymerase chain reaction method

3

Description
Leptin serum level
Timepoint
The beginning and end of the study
Method of measurement
Enzyme-linked immunosorbent assay

4

Description
Adiponectin serum level
Timepoint
The beginning and end of the study
Method of measurement
Enzyme-linked immunosorbent assay

5

Description
Resistin serum level
Timepoint
The beginning and end of the study
Method of measurement
Enzyme-linked immunosorbent assay

6

Description
Visfatin serum level
Timepoint
The beginning and end of the study
Method of measurement
Enzyme-linked immunosorbent assay

7

Description
MCP-1 serum level
Timepoint
The beginning and end of the study
Method of measurement
Enzyme-linked immunosorbent assay

8

Description
Number of headache attacks

Timepoint
The beginning and end of the study
Method of measurement
Questionnaire

9

Description
Headache duration
Timepoint
The beginning and end of the study
Method of measurement
Questionnaire

10

Description
Headache severity
Timepoint
The beginning and end of the study
Method of measurement
Questionnaire

Secondary outcomes

1

Description
sex
Timepoint
The beginning of study
Method of measurement
Questionnaire

2

Description
Weight (kg)
Timepoint
The beginning and end of study
Method of measurement
scale

3

Description
Height (m)
Timepoint
The beginning of study
Method of measurement
Height gauge

4

Description
Body mass index (kg/m²)
Timepoint
The beginning and end of study
Method of measurement
calculation

5

Description

Waist circumference (cm)

Timepoint

The beginning and end of study

Method of measurement

Meter tape

6

Description

Total energy intake (kcal)

Timepoint

The three dietary recall 24-hour questionnaires were taken at the beginning and end of the study and twice during the study, including two normal days and one day off (a total of 12 days)

Method of measurement

Dietary recall 24-hour questionnaire

7

Description

Protein intake (gr)

Timepoint

The three dietary recall 24-hour questionnaires were taken at the beginning and end of the study and twice during the study, including two normal days and one day off (a total of 12 days)

Method of measurement

Dietary recall 24-hour questionnaire

8

Description

Carbohydrate intake (gr)

Timepoint

The three dietary recall 24-hour questionnaires were taken at the beginning and end of the study and twice during the study, including two normal days and one day off (a total of 12 days)

Method of measurement

Dietary recall 24-hour questionnaire

9

Description

Fat intake (gr)

Timepoint

The three dietary recall 24-hour questionnaires were taken at the beginning and end of the study and twice during the study, including two normal days and one day off (a total of 12 days)

Method of measurement

Dietary recall 24-hour questionnaire

10

Description

Cholesterol intake (mg/d)

Timepoint

The three dietary recall 24-hour questionnaires were taken at the beginning and end of the study and twice

during the study, including two normal days and one day off (a total of 12 days)

Method of measurement

Dietary recall 24-hour questionnaire

11

Description

fiber intake (gr/d)

Timepoint

The three dietary recall 24-hour questionnaires were taken at the beginning and end of the study and twice during the study, including two normal days and one day off (a total of 12 days)

Method of measurement

Dietary recall 24-hour questionnaire

12

Description

Turmeric intake (gr/d)

Timepoint

The three dietary recall 24-hour questionnaires were taken at the beginning and end of the study and twice during the study, including two normal days and one day off (a total of 12 days)

Method of measurement

Dietary recall 24-hour questionnaire

13

Description

Vitamin D intake (ug/d)

Timepoint

The three dietary recall 24-hour questionnaires were taken at the beginning and end of the study and twice during the study, including two normal days and one day off (a total of 12 days)

Method of measurement

Dietary recall 24-hour questionnaire

14

Description

Vitamin B12 intake (ug/d)

Timepoint

The three dietary recall 24-hour questionnaires were taken at the beginning and end of the study and twice during the study, including two normal days and one day off (a total of 12 days)

Method of measurement

Dietary recall 24-hour questionnaire

15

Description

Omega 3 fatty acids intake (mg/d)

Timepoint

The three dietary recall 24-hour questionnaires were taken at the beginning and end of the study and twice during the study, including two normal days and one day off (a total of 12 days)

Method of measurement

Dietary recall 24-hour questionnaire

16

Description

Folic acid intake (mg/d)

Timepoint

The three dietary recall 24-hour questionnaires were taken at the beginning and end of the study and twice during the study, including two normal days and one day off (a total of 12 days)

Method of measurement

Dietary recall 24-hour questionnaire

17

Description

Vitamin B2 intake (mg/d)

Timepoint

The three dietary recall 24-hour questionnaires were taken at the beginning and end of the study and twice during the study, including two normal days and one day off (a total of 12 days)

Method of measurement

Dietary recall 24-hour questionnaire

18

Description

Dietary total anti-oxidant intake (mg/d)

Timepoint

The three dietary recall 24-hour questionnaires were taken at the beginning and end of the study and twice during the study, including two normal days and one day off (a total of 12 days)

Method of measurement

Dietary recall 24-hour questionnaire

19

Description

Physical activity level (MET per minute per week)

Timepoint

The two physical activity recall 24-hour questionnaires were taken at the beginning and end of the study

Method of measurement

physical activity recall 24-hour questionnaire

20

Description

Stress level

Timepoint

The beginning and the end of study

Method of measurement

The Depression, Anxiety and Stress Scale - 21 Items (DASS-21) short form

21

Description

Anxiety level

Timepoint

The beginning and the end of study

Method of measurement

The Depression, Anxiety and Stress Scale - 21 Items (DASS-21) short form

22

Description

Depression level

Timepoint

The beginning and the end of study

Method of measurement

The Depression, Anxiety and Stress Scale - 21 Items (DASS-21) short form

23

Description

Migraine family history

Timepoint

The beginning of the study

Method of measurement

Ask the patient

24

Description

The use of nonsteroidal anti-inflammatory drug

Timepoint

The end of the study

Method of measurement

Ask the patient

Intervention groups

1

Description

Intervention group: Nano-curcumin receiver group, two 40 mg capsules per day Nano-curcumin after breakfast, for 2 months, made by Sina curcumin Iran

Category

Treatment - Other

2

Description

Control group: Placebo receiver group, two capsules containing oral Pparaffin on the day after breakfast for 2 months, made by Sina curcumin Iran

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Neurology Clinic of Imam Khomeini Hospital Complex in Tehran

Full name of responsible person

Dr. Payam Sarraf

Street address

Imam Khomeini Hospital, End of Keshavarz Boulevard

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Mohsen Sedighiyan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mahmoud Djalali

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Grant name

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohsen Sedighiyan

Position

PhD student

Latest degree

Master

Other areas of specialty/work

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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

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

In addition to data on the main outcome of the study, the baseline data of participants (such as demographic and anthropometric data) will shared after blinding.

When the data will become available and for how long

The start of the data access period is 6 months after the publication of the results.

To whom data/document is available

The result of present study will be available to academic researcher and pharmaceutical companies in order to supplements production.

Under which criteria data/document could be used

The data of the present study can be used for review, systematic review and meta-analysis study.

From where data/document is obtainable

Applicants can access to study results trough e-mail address to a scientist responsible for the study: Mohsen Sedighian Email: m.sedighian86@gmail.com

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

Through sites which the manuscript will indexed, through research gate site and send e-mail to scientist responsible for the study (Mohsen Sedighian)

Comments