Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 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 nanocorcumin supplementation group and the control group (placebo-receiving group). Each nanocorcumin 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 nanocorcumin 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

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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 nanocorcumin 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<= Body Mass Index (kg/m2) =< 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: nanocorcumin 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 tow 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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1419733141
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Imamhospital@tums.ac.ir
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http://ikhc.tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Mahmoud Djalali
Street address
No. 42, Hojat doost St., Naderi St. , Keshavarz Blv.
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Phone
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Email
m.sedighiyan86@gmail.com
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
Mohsen Sedighiyan
Position
PhD student
Latest degree
Master
Other areas of specialty/work
Nutrition
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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 Sedighiyan Email: m.sedighiyan86@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 Sedighiyan)
Comments