Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Nano-curcumin on insulin resistance and serum levels of Afamin in patients with metabolic syndrome: a before-after clinical trial

Protocol summary

Study aim
To assess the effect of Nano-curcumin on insulin resistance and serum levels of Afamin in patients with metabolic syndrome

Design
This is a before-after clinical trial, in which 60 eligible patients will be assigned to the intervention and control groups

Settings and conduct
The eligible patients with metabolic syndrome who will refer to Shahid Beheshti Hospital in Hamadan City during the study period will be enrolled in the trial.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 18 to 65 years Metabolic syndrome Exclusion criteria: Diabetes Thyroid disease Liver disease Renal disease

Intervention groups
Intervention group: Tablet Nano-curcumin 80 mg/day for 2 months Control group: In comparison with before intervention

Main outcome variables
Primary outcome: Measuring the serum levels Measuring the serum levels

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N277**
Registration date: **2019-05-13, 1398/02/23**
Registration timing: **registered_while_recruiting**

Last update: **2019-05-13, 1398/02/23**
Update count: **0**

Registration date
2019-05-13, 1398/02/23

Registrant information

Name
Jalal Poorolajal

Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 81 1838 0090

Email address
poorolajal@umsha.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-03-06, 1397/12/15

Expected recruitment end date
2019-06-21, 1398/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Nano-curcumin on insulin resistance and serum levels of Afamin in patients with metabolic syndrome: a before-after clinical trial

Public title
Effect of Nano-curcumin on insulin resistance and serum levels of Afamin in patients with metabolic syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age of 18 to 65 years Metabolic syndrome

Exclusion criteria:

Diabetes Thyroid disease Liver disease Renal disease

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2019-02-23, 1397/12/04

Ethics committee reference number

IR.UMSHA.REC.1397.873

Health conditions studied

1

Description of health condition studied

Metabolic syndrome

ICD-10 code

E88.81

ICD-10 code description

Metabolic syndrome

Primary outcomes

1

Description

Measuring the serum levels of Afamin

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

Through laboratory test

2

Description

Measuring the serum levels of insulin

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

Through laboratory test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Tablet Nano-curcumin 80 mg/day for 2 months

Category

Treatment - Drugs

2

Description

Control group: In comparison with before intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital in Hamadan Cit

Full name of responsible person

Zahra Khodamoradi

Street address

Shahid Beheshti Hospital, Eram Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0283

Email
khodamoradizahra@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr Saeid Bashirian
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0717
Email
info.research@umsha.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Zahra Khodamoradi
Position
Medical Student
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0572
Email
khodamoradizahra@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Akram Ranjbar
Position
Toxicologist
Latest degree
Ph.D.
Other areas of specialty/work
Toxicology
Street address
School of Pharmacy, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0572
Email
akranjbar2015@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr Jalal Poorolajal
Position
Professor of Epidemiology
Latest degree
Ph.D.
Other areas of specialty/work
Epidemiology
Street address
School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0090
Email

poorolajal@umsha.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available