

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 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

khodamoradzahra@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

khodamoradzahra@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

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