

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of glucosamine supplementation on fasting blood glucose, fasting insulin, glycosylated hemoglobin and insulin resistance in type 2 diabetic patients: a randomized, double-blind and placebo-controlled trial

Protocol summary

Summary

The aim of this study was to determine the effect of glucosamine supplementation on fasting blood glucose level, fasting insulin, glycosylated hemoglobin and insulin resistance in type 2 diabetic patients. In this randomized, double-blind and placebo-controlled clinical trial, a total number of 58 type 2 diabetic patients were selected from Shiraz health care centers. They were randomly divided into intervention and control groups. The intervention group received 1500 mg glucosamine hydrochloride supplements once a day, while the control group received placebo capsules. They were intervened for twelve weeks. Blood samples were collected from the fasted participants at weeks of 0, 4, 8 and 12. Fasting blood glucose levels were measured at weeks of 0, 4, 8 and 12, while glycosylated hemoglobin, insulin and markers of insulin resistance (HOMA and QUICKI indices) were assessed in the weeks of 0, 8 and 12.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014031811785N2**
Registration date: **2014-04-05, 1393/01/16**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-04-05, 1393/01/16

Registrant information

Name

Mahsa Moazen

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1725 1001

Email address

moazzen@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2006-06-22, 1385/04/01

Expected recruitment end date

2006-11-22, 1385/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of glucosamine supplementation on fasting blood glucose, fasting insulin, glycosylated hemoglobin and insulin resistance in type 2 diabetic patients: a randomized, double-blind and placebo-controlled trial

Public title

Effect of glucosamine consumption on blood glucose and insulin levels in type 2 diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Confirmed diagnosis of type 2 diabetes; fasting blood sugar <150 mg/dl; glycosylated hemoglobin <7%; management of diabetes with a stable dose of hypoglycemic drugs. Exclusion criteria: Insulin therapy; having shellfish allergy; use of any medications

which alter glucose control; having history of cardiovascular diseases and thyroid disorders

Age

From **40 years** old to **79 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **58**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Central Building of Shiraz University of Medical Sciences, Zand St.

City

Shiraz

Postal code

Approval date

2006-06-07, 1385/03/17

Ethics committee reference number

CT-85-2813

Health conditions studied

1

Description of health condition studied

Type 2 diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Fasting blood glucose

Timepoint

Weeks of 0, 4, 8 and 12

Method of measurement

Auto Analyzer, unit: mg/dl

2

Description

Fasting insulin

Timepoint

Weeks of 0, 8 and 12

Method of measurement

ELISA method, unit: $\mu\text{u/ml}$

3

Description

Glycosylated hemoglobin

Timepoint

Weeks of 0, 8 and 12

Method of measurement

Ion exchange chromatography, unit: percent

4

Description

HOMA index

Timepoint

Weeks of 0, 8 and 12

Method of measurement

According to formula

5

Description

QUICKI index

Timepoint

Weeks of 0, 8 and 12

Method of measurement

According to formula

Secondary outcomes

1

Description

Body mass index

Timepoint

Weeks of 0 and 12

Method of measurement

According to formula, unit: Kg/m^2

Intervention groups

1

Description

Placebo capsules containing calcium phosphate, once a day, for twelve weeks, edible, made in Shiraz School of

Pharmacy
Category
Placebo

2

Description

Glucosamine hydrochloride supplement, 1500 mg, once a day, for 12 weeks, edible, Vitamin World Company of USA

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Naderkazemi medical center

Full name of responsible person

Street address

City

Shiraz

2

Recruitment center

Name of recruitment center

Motahari medical center

Full name of responsible person

Street address

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Sahmodini

Street address

Central Building of Shiraz University of Medical Sciences, Zand St.

City

Shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

School of Nutrition and Food Sciences, Shiraz
University of Medical Sciences

Full name of responsible person

Dr. Zohreh Mazloom

Position

Associate professor

Other areas of specialty/work

Street address

School of Nutrition and Food Sciences, Razi Blvd.

City

Shiraz

Postal code

Phone

+98 71 1725 1001

Fax

Email

zohreh.mazloom@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Nutrition and Food Sciences, Shiraz
University of Medical Sciences

Full name of responsible person

Dr. Zohreh Mazloom

Position

Associate professor

Other areas of specialty/work

Street address

School of Nutrition and Food Sciences, Razi Blvd.

City

Shiraz

Postal code

Phone

+98 71 1725 1001

Fax

Email

zohreh.mazloom@gmail.com

Web page address

Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty