

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The effects of glutamine supplementation on lipid profile, inflammatory and metabolic factors in type 2 diabetes.

Protocol summary

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Summary

This randomized clinical trial is designed to determine the effects of glutamine supplementation in type 2 diabetes. 60 patients with type 2 diabetes, oral drugs lower blood sugar using and do not have liver and renal diseases between the age range of 30-65 will be randomly assigned to 2 groups that received either glutamine or placebo (3 times a day immediately prior to the meal) for 6 weeks. fast blood sugar, GLP-1, serum insulin, c- peptide, hs-CRP, REE, HDL-C, LDL-C, total cholesterol, triglycerides, blood pressure, body composition will be measured before and 6 weeks after the intervention.

Recruitment status

Recruitment complete

Funding source

Endocrinology & Metabolism Research Center Tehran
University of Medical Sciences

Expected recruitment start date

2012-08-25, 1391/06/04

Expected recruitment end date

2012-11-24, 1391/09/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205279373N1**

Registration date: **2012-08-13, 1391/05/23**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-08-13, 1391/05/23

Registrant information

Name

Asieh Mansour

Name of organization / entity

Endocrinology & Metabolism Institute, Tehran
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

Scientific title

The effects of glutamine supplementation on lipid profile, inflammatory and metabolic factors in type 2 diabetes.

Public title

The effects of glutamine supplementation in type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patient diagnosed with type 2 diabetes based on ADA definition or who only take oral antidiabetic drug Exclusion criteria: history of drug dependence; body mass index (BMI) ≥ 35 kg/m²; history of cancer; treatment with anti-inflammatory; corticosteroid; hormonal or antibiotic agents; a restrictive diet or weight change ≥ 5 kg during the 3 months prior to study; systolic blood pressure > 160 mmHg and/or diastolic blood pressure > 90 mmHg; fatty liver disease; liver or kidney disease; autoimmune disease; pregnancy and lactation; any change in treatment with oral hypoglycemic; anti hypertensive and antilipid agents during the study; use of weight loss

medications; HbA1C >8

Age
From **30 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

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
Endocrinology & Metabolism Research Institute
Tehran University of Medical Sciences

Street address
5th Floor, Shariati Hospital, North Kargar
Ave, 1411413137 Tehran Iran

City
Tehran

Postal code

Approval date
2012-07-04, 1391/04/14

Ethics committee reference number
EC-00197

Health conditions studied

1

Description of health condition studied
Diabetes mellitus

ICD-10 code
E11

ICD-10 code description
Non-insulin dependent diabetes mellitus

Primary outcomes

1

Description
fast blood sugar

Timepoint
Before and 6 weeks after the intervention

Method of measurement
mg/ dl / enzymatic

2

Description
GLP-1 (Glucagon- like peptide-1)

Timepoint
Before and 6 weeks after the intervention

Method of measurement
pmol/ l / ELISA

3

Description
serum insulin

Timepoint
Before and 6 weeks after the intervention

Method of measurement
pmol/ l / IRMA method

4

Description
serum c peptide

Timepoint
Before and 6 weeks after the intervention

Method of measurement
mg/ l

5

Description
Hs- CRP

Timepoint
Before and 6 weeks after the intervention

Method of measurement
ELSA

6

Description
Resting energy expenditure

Timepoint
Before and 6 weeks after the intervention

Method of measurement
indirect calorimetry

Secondary outcomes

1

Description
srum glutamine

Timepoint
Before and 6 weeks after the intervention

Method of measurement

spectrophotometric

2

Description

blood pressure

Timepoint

Before and 6 weekes after the intervention

Method of measurement

blood pressure,sphygmomanometer

3

Description

total cholesterol

Timepoint

Before and 6 weekes after the intervention

Method of measurement

mg/ dl

4

Description

HDL-C

Timepoint

Before and 6 weekes after the intervention

Method of measurement

mg/ dl

5

Description

LDL-C

Timepoint

Before and 6 weekes after the intervention

Method of measurement

mg/dl

6

Description

Hb A1C

Timepoint

Before and 6 weekes after the intervention

Method of measurement

fast HbA1c serum level,Chromatography

7

Description

serum creatinine

Timepoint

Before and 6 weekes after the intervention

Method of measurement

mg/dl

8

Description

body composition

Timepoint

Before and 6 weekes after the intervention

Method of measurement

Tanita body composition analyzer

9

Description

triglyceride

Timepoint

Before and 6 weeks after the intervention

Method of measurement

mg/dl

Intervention groups

1

Description

glutamine (3 times a day for 6 weeks)

Category

Treatment - Drugs

2

Description

cellulose (3 times a day for 6 weeks)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Doctor Shariati Specialized Clinic

Full name of responsible person

Saeed Hosseini

Street address

5th Floor,Shariati Hospital,North Kargar
Ave,1411413137 Tehran Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Endocrinology & Metabolism Research Institute,
Tehran University of Medical Sciences

Full name of responsible person

Doctor Ramin Heshmat

Street address

5th Floor,Shariati Hospital,North Kargar
Ave,1411413137,Tehran,Iran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Endocrinology & Metabolism Research Institute, Tehran

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
Endocrinology & Metabolism Research Institute
Tehran University of Medical Sciences
Full name of responsible person
Asieh Mansour
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Researcher/ MSc student of nutrition.Tehran
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Person responsible for updating data

Contact

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