

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Effect of Brewers yeast on glycosylated hemoglobin, insulin resistance, insulin sensitivity and blood pressure in patients with type 2 diabetes mellitus

Protocol summary

Summary

In a double-blind placebo-controlled clinical trial aimed to determine the effects of brewers yeast supplementation on insulin resistance, insulin sensitivity, glycosylated hemoglobin and blood pressure in type 2 diabetic patients, 80 patients (63 women and 21 men) with a history of diabetes for at least 2 years, aged 35-55 years, without any record of hepatitis, cardiovascular, renal and Parkinson's diseases, gout and depression disorder in the last year were randomly selected from those referring to the Dezful ganjavian diabetes clinic. They were divided into 2 groups by ABAB blockes based on sex and glycosylated hemoglobin. Participants of the brewer's yeast group received 1800 mg Brewer's yeast (two 300 mg tablets three times daily) and placebo group received equal quantities of pills containing excipient without brewer's yeast for the same period of time. Initial and final blood pressure were measured. Moreover, fasting blood samples were taken at baseline and after 12 weeks to be analyzed for glycemic indices and serum lipoprotein .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138807062513N1**

Registration date: **2012-07-25, 1391/05/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-07-25, 1391/05/04

Registrant information

Name

Payam Hoseinzadeh

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8895 4911

Email address

p_hoseinzadeh@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for Research, Tehran University of Medical Sciences

Expected recruitment start date

2009-11-22, 1388/09/01

Expected recruitment end date

2010-03-11, 1388/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Brewers yeast on glycosylated hemoglobin, insulin resistance, insulin sensitivity and blood pressure in patients with type 2 diabetes mellitus

Public title

Effect of Brewers yeast on blood glucose level and blood pressure in patients with type 2 diabetes mellitus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: History of at least 2 years clinically diagnosed type 2 diabetes mellitus; taking oral

hypoglycemic drugs ; Fasting blood glucose at least more than 125 mg/dl; Not consuming brewers yeast during the last 3 months; Aged 35-55 years; Signing the informed consent form (attached). Exclusion criteria: History of hepatitis, cardiovascular, renal and Parkinson's diseases, gout and depression disorder, A record of angina pectoris, myocardial and cerebral infarction during the last year; History of infectious disease or common cold during the last 4 weeks; Regular consumption of anti-inflammatory drugs (steroid or non-steroid) or monoamine oxidase inhibitors; Insulin therapy; Consumption of brewers yeast or placebo less than 12 weeks; Any side effects due to supplementation; Change in diet or hypoglycemic drugs; Unwilling to continue taking supplementation.

Age

From **35 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

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**

Tehran University of Medical Sciences Ethics Committee

Street address

Keshavarz Blvd., Corner of Ghods St.

City

Tehran

Postal code**Approval date**

2010-03-02, 1388/12/11

Ethics committee reference number

45951

Health conditions studied**1****Description of health condition studied**

Non-insulin-dependent diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes**1****Description**

Fasting Blood Sugar

Timepoint

Baseline, After 12 weeks

Method of measurement

Blood Analysis: GOD / PAP method

2**Description**

Glycosylated hemoglobin

Timepoint

Baseline, After 12 weeks

Method of measurement

Blood Analysis: boronate affinity assay

3**Description**

HOMA-IR (homeostatic model assessment of insulin resistance)

Timepoint

Baseline, After 12 weeks

Method of measurement

computed as fasting plasma glucose (mmol/L) × fasting serum insulin (mU/L) / 22.5

4**Description**

QUICKI (quantitative insulin sensitivity check index)

Timepoint

Baseline, After 12 weeks

Method of measurement

calculated as $1 / [\log \text{insulin } (\mu\text{U/ml}) + \log \text{glucose } (\text{mg/dl})]$

5**Description**

Systolic Blood pressure

Timepoint

Baseline, After 12 weeks

Method of measurement

Mercury sphygmomanometer

6**Description**

Diastolic blood pressure

Timepoint

Baseline, After 12 weeks

Method of measurement

Mercury sphygmomanometer

Secondary outcomes

1

Description

Triglyceride

Timepoint

Baseline, After 12 weeks

Method of measurement

Blood Analysis: colorimetric method

2

Description

Total cholesterol

Timepoint

Baseline, After 12 weeks

Method of measurement

Blood Analysis: colorimetric method

3

Description

High Density Lipoprotein (HDL-c)

Timepoint

Baseline, After 12 weeks

Method of measurement

Blood Analysis: Enzymatic method

4

Description

Low Density Lipoprotein (LDL-c)

Timepoint

Baseline, After 12 weeks

Method of measurement

Blood Analysis: Enzymatic method

5

Description

Height

Timepoint

Baseline

Method of measurement

stadiometer (seca 206)

6

Description

Weight

Timepoint

Baseline, After 12 weeks

Method of measurement

Digital scale (seca762)

7

Description

Body Mass Index (BMI)

Timepoint

Baseline, After 12 weeks

Method of measurement

Calculate

8

Description

Three days food intakes

Timepoint

Baseline, After 12 weeks

Method of measurement

24-hour food recall

Intervention groups

1

Description

Intervention group: receiving brewer's yeast tablet (two 300mg tablets three times daily, total 1800 mg) for 12 weeks

Category

Treatment - Drugs

2

Description

control group: receiving placebo tablet (two 300mg tablets three times daily, total 1800 mg) for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ganjavian Hospital

Full name of responsible person

Farideh Taheri

Street address

Clinic of diabetes, 2nd floor, Ganjavian hospital, Andimeshk-Dezful road

City

Dezful

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Science

Full name of responsible person

Dr. Akbar Fotoohi

Street address

Vice-chancellor for Research, 6th floor, Tehran University of Medical Sciences, Central building, Keshavarz blvd.

City

Tehran

Grant name**Grant code / Reference number**

10428

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

Yes

Title of funding source

Tehran University of Medical Science

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 Public Health, Tehran University of Medical Sciences

Full name of responsible person

Dr. Abolghassem Djazayeri

Position

Professor of Nutrition/PhD

Other areas of specialty/work**Street address**

Nutrition and Biochemistry Department, Health Faculty, Tehran University of Medical Sciences, Poorsina street

City

Tehran

Postal code**Phone**

+98 21 6644 2095

Fax**Email**

djazayeri@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

School of Public Health, Tehran University of Medical Sciences

Full name of responsible person

Dr. Mahmoud Jalali

Position

Professor of Biochemistry/PhD

Other areas of specialty/work**Street address**

Nutrition and Biochemistry Department, Health Faculty, Tehran University of Medical Sciences, Poorsina Street

City

Tehran

Postal code**Phone**

+98 21 8897 4463

Fax**Email**

jalalimahmoud@hotmail.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Tehran University Of Medical Sciences

Full name of responsible person

Payam Hoseinzadeh

Position

MSc.Student

Other areas of specialty/work**Street address**

No.805, Azarbayjan st.

City

Tehran

Postal code

141556446

Phone

+98 21 6690 1510

Fax**Email**

payam07@ymail.com

Web page address

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