

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

A Clinical trail to compare White Button Mushroom (*Agaricus Bisporus*) powder with corn starch on levels of glycemic indices, lipid profile , serum hs - CRP, ergothioneine and total antioxidant capacity in type 2 diabetic patients

Protocol summary

Summary

The objective of this study is the evaluation the effects of White Button Mushroom (*Agaricus Bisporus*) powder on some of glycemic indices, lipid profile, serum levels of hs-CRP, ergothioneine and total antioxidant capacity in type 2 diabetic patients. In this double blind randomized clinical trial, 44 diabetic patients are selected and allocated to two groups involve intervention (n=22) and control (n=22) groups. Blinding will be implemented on patients and researchers. The period of intervention is 8 weeks. Main inclusion criteria: type 2 diabetic patients who have been suffering from the disease for at least 2 years and have been using diabetic drugs for more than 6 month. Main Exclusion criteria: using insulin therapy, allergic to mushrooms and major medical conditions. The intervention group receives mushroom powder (16 gr daily) and the control group receives corn starch powder as placebo (16 gr daily) for 8 weeks. Some demographic data including age, sex; anthropometric indices such as weight, height, BMI, waist and hip circumference; biochemical indices including fasting blood glucose, total antioxidant capacity, high sensitive C-reactive protein and a 24 hour recall are evaluated pre and post intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017062534760N1**
Registration date: **2017-09-27, 1396/07/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-09-27, 1396/07/05

Registrant information

Name

Hadiseh Hashemi yosefabad

Name of organization / entity

Ahvaz Jundishapur University of Medical Science

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2017-04-18, 1396/01/29

Expected recruitment end date

2017-07-20, 1396/04/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Clinical trail to compare White Button Mushroom (*Agaricus Bisporus*) powder with corn starch on levels of glycemic indices, lipid profile , serum hs - CRP, ergothioneine and total antioxidant capacity in type 2 diabetic patients

Public title

Effect of White Button Mushroom in treatment of diabetic patients with type 2 diabetes mellitus

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: type 2 diabetic patients who have been suffering from the disease for at least 2 years and have been using diabetic drugs for more than 6 month; BMI between 20 and 35 kg/m². Exclusion criteria: using insulin therapy; Smoking; pregnancy; breast feeding; Weight loss greater than 10% of body weight in the past 6 months; being currently on a weight-loss diet or program; allergic to latex; allergic to mushrooms; consuming mushroom more than once or twice a week; major medical conditions (such as renal failure, heart failure, inflammatory diseases, hepatitis); using immunosuppressive; NSAIDs; diuretic; estrogen medications; using any dietary supplements including antioxidant, fiber, omega 3.

Age

From **23 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

Assignment of patients to each groups is done by random block method using block of size 4.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Ahvaz Jundishapur University of Medical Science

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan highway, Ahvaz, Khosetan, Iran

City

Ahvaz

Postal code**Approval date**

2017-04-18, 1396/01/29

Ethics committee reference number

IR.AJUMS.REC.1396.381

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

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

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

Fasting blood glucose

Timepoint

before and after intervention

Method of measurement

Using enzymatic kit method

2**Description**

Insulin

Timepoint

before and after intervention

Method of measurement

EIISA

3**Description**

Fructosamine

Timepoint

before and after intervention

Method of measurement

EIISA

4**Description**

LDL cholestrol

Timepoint

before and after intervention

Method of measurement

Using enzymatic kit method

5**Description**

HDL cholestrol

Timepoint

before and after intervention

Method of measurement

Using enzymatic kit method

6

Description

VLDL cholesterol

Timepoint

before and after intervention

Method of measurement

Using enzymatic kit method

7

Description

Triglyceride

Timepoint

before and after intervention

Method of measurement

Using enzymatic kit method

8

Description

Total cholesterol

Timepoint

before and after intervention

Method of measurement

Using enzymatic kit method

9

Description

hs-CRP

Timepoint

before and after intervention

Method of measurement

EIISA

10

Description

TAC

Timepoint

before and after intervention

Method of measurement

EIISA

11

Description

Ergothioneine

Timepoint

before and after intervention

Method of measurement

HPLC

Secondary outcomes

empty

Intervention groups

1

Description

Intervention: The intervention group receive 16 gr

mushroom powder twice a day with food (8 grams per meal), daily for 8 weeks.

Category

Other

2

Description

Control: The control group receive 16 gr corn starch powder twice a day with food (8 grams per meal), daily for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Clinic of Golestan Hospital

Full name of responsible person

Dr Mehrnoosh Zakerkish

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Ahvaz Jundishapur University of Medical Sciences, Golestan highway, Ahvaz, Khosetan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr. Nader Saki

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research, Ahvaz Jundishapur 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

Ahvaz Jundishapur University of Medical Science

Full name of responsible person

Hadiseh Hashemi yusefabad

Position

Master student in Nutrition

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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