

# 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

###### **Country**

Iran (Islamic Republic of)

###### **Phone**

+98 917 145 7681

###### **Email address**

hashemi.h@ajums.ac.ir

##### **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/m<sup>2</sup>. 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

#### **Street address**

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

#### **City**

Ahvaz

## **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

#### **Street address**

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#### **City**

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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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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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**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