Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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
ElISA

3

Description
Fructosamine
Timepoint
before and after intervention
Method of measurement
ElISA

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 cholestrol
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 cholestrol
Timepoint
before and after intervention
Method of measurement
Using enzymatic kit method

9

Description
hs-CRP
Timepoint
before and after intervention
Method of measurement
ElISA

10

Description
TAC
Timepoint
before and after intervention
Method of measurement
ElISA

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
Ahvaz Jundishapur University of Medical Sciences, Golestan highway, Ahvaz, Khosetan,Iran
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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
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Position
Master student in Nutrition

Other areas of specialty/work

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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