Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Effects of Arctium Lappa root on values of blood sugar, amylase, antioxidants, lipid ratios and insulin resistance in individuals with type 2 diabetes

Protocol summary

Study aim
Effects of Arctium Lappa root on Serum levels of some biochemical variables in individuals with type 2 diabetes

Design
In this double blind study, a total number of 80 people with type 2 diabetes will be selected.They will be divided into two groups of Arctium Lappa root and control (placebo) by simple randomization method. They will be matched in age and BMI.

Settings and conduct
The purpose of the study and how to do it will be explained to patients and Written consent will be obtained from them to participate in the study.Blood samples are taken from patients at the beginning of the study(Sampling is done in the clinic)and Factors such as blood sugar, fat, etc. are measured in the blood(Invoicing is done in the university laboratory) .Then , the herbal medicine will be used in the participants for 12 weeks, and after this period, blood samples will be taken again and the factors will be measured again in order to evaluate the effect of the medicine. Patients will not be aware of the type of drug and the statistician will not be aware of the type of groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria are:Diagnosis of type 2 diabetes over two years (FBS>125 ، 2hpp>200 , HbA1c>6.5),No change in the dose of oral blood glucose lowering medicine during testing,Maintain physical activity and diet as usual during the test,No infection to liver, gastrointestinal and kidney diseases. Exclusion criteria: People who receive vitamin supplements during the last three months, People treated with insulin and other hormones and People who are pregnant and breastfeeding.

Intervention groups
Recipient group of Arctium Lappa root (One 460 mg capsule per day) and recipient group contains active charcoal with the same dose

Main outcome variables
values of blood sugar, amylase, antioxidants, lipid ratios and insulin resistance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210222050455N1**
Registration date: **2021-04-22, 1400/02/02**
Registration timing: **registered_while_recruiting**

Last update: **2021-04-22, 1400/02/02**
Update count: **0**

Registration date
2021-04-22, 1400/02/02

Registrant information

Name
Masoume Ghorbani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 86 3417 3638

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-04, 1400/01/15

Expected recruitment end date
2021-04-30, 1400/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Arctium Lappa root on values of blood sugar, amylase, antioxidants, lipid ratios and insulin resistance in individuals with type 2 diabetes

Public title

Effects of Arctium Lappa root in individuals with type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of type 2 diabetes over two years (FBS>125 ، 2hpp>200 و HbA1c>6/5) No change in the dose of oral blood glucose lowering during testing Maintain physical activity and diet as usual during the test No liver, gastrointestinal and kidney diseases Lack of treatment with anticoagulants Do not take anti hypertensive drugs and diuretics No alcohol No smoking No allergies

Exclusion criteria:

People who receive vitamin supplements during the last three months People treated with insulin and other hormones People who are pregnant and breastfeeding

Age

From **40 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants, healthcare providers and outcome assessors are blinded.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, healthcare providers and outcome assessors are blinded.The drug and placebo are packaged in similar packages. The treatment group and placebo group will not be aware of the type of intervention they receive. The statistician will not be informed about the grouping done

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Arak University of Medical Sciences,Basij square,Sardasht,Arak

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Province

Markazi

Postal code

3848176941

Approval date

2021-01-24, 1399/11/05

Ethics committee reference number

IR.ARAKMU.REC.1399.309

Health conditions studied

1

Description of health condition studied

type 2 diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

Fasting glucose

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Colorimetric

2

Description

Amylase

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Spectrophotometry

3

Description

Catalase

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Spectrophotometry

4

Description

MDA

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Calorimetry

5

Description

Total antioxidant capacity (TAC)

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Calorimetry

6

Description

Insulin

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Eliza

7

Description

HbA1C

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Calorimetry

8

Description

Lipid profile

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Calorimetry

9

Description

Lipid ratios(Total Cholesterol/HDl-c and LDL-c/HDl-c)

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Formula

10

Description

HOMA-B

Timepoint

Before and after 12 weeks of intervention

Method of measurement

HOMA-IR model evaluation

Secondary outcomes

1

Description

Body mass index (BMI)

Timepoint

Before and after 12 weeks of intervention

Method of measurement

weight/height

Intervention groups

1

Description

Intervention group: One capsule Arctium Lappa root (460 mg) per day for 12 weeks

Category

Treatment - Drugs

2

Description

Control group: One capsule placebo charcoal (460 mg) day for 12 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar Specialized Clinic

Full name of responsible person

Dr. Javad Javaheri

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

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Research@arakmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Only results of main outcomes
When the data will become available and for how long
Six months after publishing of the results
To whom data/document is available
Only for academic staffs and universities researches
Under which criteria data/document could be used
Only for international and between universities researches
From where data/document is obtainable
Ali Khosrowbeygi a.khosrowbeygi@arakmu.ac.ir
What processes are involved for a request to access data/document
1. Requesting a team work clinical trial via email. 2. Approving the proposal. 3. Registration of the trial
Comments
No comments