

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)

Phone

+98 86 3417 3638

Email address

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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

City

Arak

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
Street address
Seyed Mosque three ways,Imam street
City
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Postal code
3134877179
Phone
+98 86 3223 3823
Fax
Email
javaheri_115@yahoo.com

2

Recruitment center
Name of recruitment center
Imam Reza Specialized Clinic
Full name of responsible person
Dr. Javad Javaheri

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After blood transfusion organization,Shahid Shiroodi Street

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Fax**Email**

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Mohammad Arjomandzadegan

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Email

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**

Arak University of Medical Sciences

Full name of responsible person

Masoume Ghorbani

Position

Student

Latest degree

Master

Other areas of specialty/work

Biochemistry

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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