Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of Curcumex on fasting plasma glucose, HbA1c, Lipid profile, Insulin resistance and Inflammatory biomarkers in patients with type 2 diabetes mellitus: A randomized double blind clinical Trial.

Protocol summary

Study aim
The effect of Curcumex on fasting blood glucose, HbA1c, Lipid profile, Insulin resistance and Inflammatory biomarkers in patients with type 2 diabetes mellitus: A randomized double blind Clinical Trial

Design
Two arm parallel group randomised trial Double blinded

Settings and conduct
A study on diabetes is performed in Ahwaz Golestan Hospital in a randomized, double blind clinical trial, The study compares the effect of Curcumex and placebo in two parallel groups of 30 patients

Participants/Inclusion and exclusion criteria
Inclusion criteria: Baseline A1c <9% Fasting blood glucose is between 200-126 mg / dl Patients only use oral hypoglycemic drugs Duration of diagnosis of diabetes is less than 10 years Exclusion criteria: Pregnancy and lactation Insulin treatment Sensitization and allergy to black pepper or other ingredients in combination Significant renal and hepatic failure

Intervention groups
The intervention group includes people with type 2 diabetes who receive curcumex intervention. The control group includes people with type 2 diabetes who receive placebo.

Main outcome variables
Fasting plasma glucose, HbA1c, Lipid profile, Insulin resistance and Inflammatory biomarkers in patients with type 2 diabetes mellitus

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181028041483N1**
Registration date: **2019-01-16, 1397/10/26**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-16, 1397/10/26**
Update count: **0**

Registration date
2019-01-16, 1397/10/26

Registrant information

Name
Ali Asghar Hemmati

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 3373 8382

Email address
hemmati-aa@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-11-22, 1397/09/01

Expected recruitment end date
2019-03-21, 1398/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Curcumex on fasting plasma glucose, HbA1c, Lipid profile, Insulin resistance and Inflammatory biomarkers in patients with type 2 diabetes mellitus: A randomized double blind clinical Trial.

Public title

The effect of Curcumex on Type 2 diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Baseline A1c <9% Fasting blood glucose is between 200-126 mg / dl Patients only use oral hypoglycemic drugs Duration of diagnosis of diabetes is less than 10 years

Exclusion criteria:

Pregnancy and lactation Insulin treatment Sensitization and allergy to black pepper or other ingredients in combination Significant renal and hepatic failure

Age

From **30 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Method of randomization: block Unit of randomization : individual Randomization strata in stratified randomization:HbA1C Tools used in randomization : sealed envelops How the random sequence was built: table of random numbers Whether of not allocation concealment was carried out:Sealed envelopes will be opaque

Blinding (investigator's opinion)

Double blinded

Blinding description

participants, principle investigator, outcome assessor,data and safety monitoring board

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of the Jundishapur University of Medical Sciences Ahwaz

Street address

Esfand Ave, Farvardin Blvd,Golestan

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2018-10-23, 1397/08/01

Ethics committee reference number

IR.AJUMS.REC.1397.522

Health conditions studied

1

Description of health condition studied

diabetes mellitus type 2

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The percentage of people who have fasting blood glucose (200-126 mg / dL)

Timepoint

Before the intervention begins and Day 90

Method of measurement

Parsazmoon's FBS kit

2

Description

The percentage of people who have glycosylated hemoglobin (9% -7%)

Timepoint

Before the intervention begins and Day 90

Method of measurement

Diazyme's HbA1c kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Curcumex 2 times a day for 3 months

Category

Treatment - Drugs

2

Description

Control group: Placebo ,2 times a day for 3 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Golestan Hospital

Full name of responsible person

Ali Asghar Hemmati

Street address

Ahvaz ,Farvardin Blvd, Golestan Hospital

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Phone

+98 61 3374 3001

Email

Hemmati_aa@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Ali Asghar Hemmati

Street address

Esfand Ave, Farvardin Blvd,Golestan

City

Ahvaz

Province

Khouzestan

Postal code

61359-39937

Phone

+98 61 3373 8382

Email

Hemmati-aa@ajums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Ali Asghar Hemmati

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Jundishapur University, Esfand Ave, Farvardin Blvd, Golestan, Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

61359-39937

Phone

+98 61 3373 8382

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Person responsible for scientific inquiries

Contact

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Ahvaz

Province

Khouzestan

Postal code

61359-39937

Phone

+966 13 373 8382

Email

Hemmati-aa@ajums.ac.ir

Person responsible for updating data

Contact

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Ahvaz University of Medical Sciences
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Ali Asghar Hemmati
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Professor
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Email
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available