

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of anti-oxidant and anti-inflammatory effects of Curcumin in type 2 diabetes patients

Protocol summary

Summary

Type 2 diabetes mellitus (DM) is a chronic metabolic disorder. The prevalence of type 2 DM has been drastically increasing all over the world. Type 2 DM is characterized by insulin insensitivity as a result of insulin resistance, decreasing insulin production, and eventual pancreatic beta-cell failure. Increased inflammatory markers from fat, and oxidative factors, have all been implicated in the pathogenesis of type 2 DM. Curcumin is a naturally occurring polyphenol isolated from the rhizomes of the *Curcuma longa* herb (turmeric), which possesses anti-oxidant, and anti-inflammatory anti-diabetic properties. The aim of this study is to evaluate the anti-inflammatory, anti-oxidant and anti-diabetic effects of Curcumin in a randomized double blind placebo controlled trial included subject (n=120) with criteria of type 2 DM. All subjects will randomly assigned to receive either Curcumin or placebo capsules twice a day for 3months. To assess anti-diabetic, anti-oxidant and anti-inflammatory effects of Curcumin, changes in serum parameters including FBS, fasting insulin, C-peptide, HbA1c, Superoxide dismutase (SOD), plasma Total Antioxidant Capacity (TAO), Malondialdehyde (MDA), C reactive protein (CRP), leptin, adiponectin, TNF- α , ghreline, glucagon like peptide 1 (GLP-1), aspartate transaminase (AST), alanine transaminase (ALT) and serum creatinine will be monitored at the baseline and after 3month of treatments. Finally, the results will be analyzed by SPSS 20 software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201505301165N4**

Registration date: **2015-06-07, 1394/03/17**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-06-07, 1394/03/17

Registrant information

Name

Yunes Panahi

Name of organization / entity

Baqiyatallah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8821 1524

Email address

yunespanahi@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Baqiyatallah University of Medical Sciences

Expected recruitment start date

2015-06-10, 1394/03/20

Expected recruitment end date

2015-10-12, 1394/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of anti-oxidant and anti-inflammatory effects of Curcumin in type 2 diabetes patients

Public title

Effect of Curumin (tumeric) on type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: diagnosis of type 2 diabetes (FBS ≥ 126 mg/dl, HbA1C $\geq 6.5\%$); type 2 diabetes patients under standard anti-diabetics agents; adult patients (18 to 65 year old). Exclusion criteria: pregnancy or breast feeding; lack of compliance with the study medication; impossibility to give informed consent; participation on an other concomitant clinical trial; presence of malignancies; chronic liver disease (ALT ≥ 3 folds of upper limit of normal value range; renal failure (serum creatinine ≥ 2.0 mg/dL or on dialysis); subjects receiving hormonal agents; subjects receiving other herbal medicines; subjects with secondary causes of hyperglycemia (receiving steroids or with pancreatic cancer) subjects with acute infections or chronic inflammatory diseases (rheumatoid arthritis); hypersensitivity to the study medication; endocrine disease (hypothyroidism or hyperthyroidism); obsessive compulsive disorder.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Baqiyatallah University of Medical Sciences

Street address

Vanak

City

Tehran

Postal code**Approval date**

2015-05-06, 1394/02/16

Ethics committee reference number

IR.RMSU.REC.1394.31

Health conditions studied**1****Description of health condition studied**

type 2 diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes**1****Description**

Fasting insulin

Timepoint

at baseline and 3 months after intervention

Method of measurement

pmol/L

2**Description**

Fasting Blood Sugar

Timepoint

at baseline and 3 months after intervention

Method of measurement

mg/dl

3**Description**

C peptide

Timepoint

at baseline and 3 months after intervention

Method of measurement

ng/ml

4**Description**

HbA1C

Timepoint

at baseline and 3 months after intervention

Method of measurement

percent

5**Description**

MDA

Timepoint

at baseline and 3 months after intervention

Method of measurement

nmol/ml

6**Description**

TNF- α

Timepoint

at baseline and 3 months after intervention
Method of measurement
pg/ml

7

Description
Superoxidase dismutase (SOD)
Timepoint
at baseline and 3 months after intervention
Method of measurement
U/ml

8

Description
plasma Total Antioxidant Capacity (TAO)
Timepoint
at baseline and 3 months after intervention
Method of measurement
nmol/mg

9

Description
Leptin
Timepoint
at baseline and 3 months after intervention
Method of measurement
ng/ml

10

Description
Adiponectin
Timepoint
at baseline and 3 months after intervention
Method of measurement
ng/ml

11

Description
Ghreline
Timepoint
at baseline and 3 months after intervention
Method of measurement
pmol/L

12

Description
Glucagon like peptide-1
Timepoint
at baseline and 3 months after intervention
Method of measurement
pmol/L

13

Description
C Reactive Protein (CRP)
Timepoint
at baseline and 3 months after intervention

Method of measurement
mg/dl

Secondary outcomes

1

Description
Body Mass Index (BMI)
Timepoint
at the baseline and 3 month after treatment
Method of measurement
kg/m2

2

Description
Alanine transaminase (ALT)
Timepoint
at the baseline and 3 month after treatment
Method of measurement
U/L

3

Description
Aspartate transaminase (AST)
Timepoint
at the baseline and 3 month after treatment
Method of measurement
U/L

4

Description
Serum Creatinine
Timepoint
at the baseline and 3 month after treatment
Method of measurement
mg/dl

Intervention groups

1

Description
Intervention: Curcumin capsule, twice a day, until 3 months
Category
Treatment - Drugs

2

Description
Control: Placebo capsule, 500 mg twice a day, until 3 months
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes clinic, Baqiyatallah hospital

Full name of responsible person

Dr. Yunes Panahi

Street address

Vanak, Mollasadra

City

Tehran

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ebrahimsahebi@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Chemical Injuries Research Center, Baqiyatallah
University of Medical Sciences

Full name of responsible person

Dr. Yunes Panahi

Street address

Vanak, Mollasadra

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Chemical Injuries Research Center, Baqiyatallah
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

Chemical Injuries Research Center, Baqiyatallah
University of Medical Sciences

Full name of responsible person

Ebrahim Sahebi

Position

Doctorate of Pharmacy

Other areas of specialty/work

Person responsible for scientific inquiries

Contact

Name of organization / entity

Chemical Injuries Research Center, Baqiyatallah
University of Medical sciences

Full name of responsible person

Yunes Panahi

Position

Clinical Pharmacist

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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