Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 ≥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
perecent

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

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
Vanal, 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
Street address
Vanak, Mollasadra
City
Tehran
Postal code
Phone
+98 21 8248 2516
Fax
Email
ebrahimsahebi@yahoo.com
Web page address

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
Street address
Mollasadra, Vanak
City
Tehran
Postal code
Phone
+98 21 8248 2516
Fax
Email
yunespanahi@yahoo.com
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