

Curcuminoid supplementation on type 2 diabetes

Submission date 03/10/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 25/10/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 16/05/2022	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
2009007

Study information

Scientific Title
Effects of curcuminoids on blood glucose, lipids, serum adipocyte fatty acid-binding protein and lipoprotein lipase in patients with type 2 diabetes: a double-blind, placebo-controlled trial

Study objectives

The natural compounds curcuminoids, including curcumin, demethoxycurcumin and bisdemethoxycurcumin, have a broad spectrum of health benefits including hypolipidemic, hypoglycemic effects. As diabetes is associated with impaired lipid metabolism, the improvement of lipid profile may explain at least in part the benefits of curcuminoids on diabetes.

Our previous study confirmed that curcumin improved insulin resistance in part by decreasing plasma FFAs and increasing fatty acid oxidation in skeletal muscle of diabetic rats. However, reports about the effect of curcuminoids on type 2 diabetes in human are extremely limited.

We hypothesized that curcuminoids would increase insulin sensitivity partly by promoting fatty acid oxidation in patients with type 2 diabetes.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Medical Ethics Committee of Public Health College, Harbin Medical University, approved on 20th September 2009 (ref: 2009007)

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Type 2 diabetes

Interventions

Eligible subjects were first sorted by blood glucose concentration and then randomised into two groups with a block size of 2, with random numbers generated by SPSS.

The subjects in the curcuminoids group received a 150 mg curcuminoid capsule twice daily (30 minutes after breakfast and supper respectively) for a total intake of 300 mg/d curcuminoids (the purity had been confirmed to be 97.49% by HPLC: curcumin 36.06%; demethoxycurcumin, 18.85%; bisdemethoxycurcumin, 42.58%).

The subjects in placebo group took capsules with placebo (starch) instead of curcuminoids at the same frequency and amount.

The intervention lasted for 3 months.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Curcuminoids

Primary outcome(s)

1. The effects of curcuminoids on glucose metabolism: fasting glucose and insulin, 2-hour post prandial glucose , HOMA-IR and HbA1c(%)
2. The effects of curcuminoids on lipis metabolism:
 - 2.1. Serum cholesterol, triacylglycerol, HDL-C, LDL-C, Apo A-I and Apo B
 - 2.2. Serum LPL and AFABP
 - 2.3. Serum FFA profile
 - 2.4. Severity of fatty liver

Key secondary outcome(s)

1. Baseline characteristics: age, gender, BMI, waist circumference, waist-to-hip ratio, diabetes duration, blood pressure, drug treatment, cigarette use and physical activity level
2. Daily intake of nutrients by the subjects at baseline and after 3-month intervention
3. Blood biochemistry characteristics of the subjects at baseline and after 3-month intervention: red blood cell, white blood cell, hemoglobin, total protein, albumin, urea nitrogen, creatinine, alanine transaminase and aspartate transminase

Completion date

10/01/2010

Eligibility

Key inclusion criteria

1. Aged 18 - 65 years, both male and female
2. Type 2 diabetes with fasting blood glucose greater than or equal to 7.0 mmol/L or postprandial blood glucose greater than or equal to 11.1 mmol/L
3. Current optimal therapeutic regimens lasting for at least 6 months

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

100

Key exclusion criteria

1. A history of type 1 diabetes, malignancies, thyroid or any other endocrine diseases likely to interfere with the study
2. Diabetic ketosis acidosis and infection in recent 3 months
3. Pregnancy or breastfeeding
4. Information incompleted or unwillingness to attempt to comply with the intervention

Date of first enrolment

10/10/2009

Date of final enrolment

10/01/2010

Locations

Countries of recruitment

China

Study participating centre

157 Baojian Road

Harbin

China

150081

Sponsor information

Organisation

Public Health College - Harbin Medical University (China)

ROR

<https://ror.org/05jscf583>

Funder(s)

Funder type

Government

Funder Name

National Natural Science Foundation of China (China) (ref: 30810107)

Alternative Name(s)

Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wéiyuánhùi, , NSFC, NNSF, NNSFC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

China

Funder Name

National High Technology Research and Development Program of China (China) - 863 program)
(ref: 2010AA023002)

Funder Name

Scientific Research Fund of Heilongjiang Provincial Education Department (China) (ref: 1154z1007)

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/11/2014	16/05/2022	Yes	No