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Curcuminoid supplementation on type 2 diabetes

Submission date	Recruitment status	[_] Prospectively registered
03/10/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/10/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/05/2022	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 Committe of Public Health College, Harbin Medical University, approved on 20th September 2009 (ref: 2009007)

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

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 measure
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

Secondary outcome measures
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

Overall study start date
10/10/2009

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

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
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Sponsor information

Organisation
Public Health College - Harbin Medical University (China)

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Sponsor type
University/education

Website
http://yxzy.hrbmu.edu.cn/gongwei/

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 Wěiyuánhuì, 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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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