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A study of supplementation with Curcumin to Diabetics

Submission date	Recruitment status	[ ] Prospectively registered
27/04/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
14/06/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
21/09/2010	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

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
003

Study information

Scientific Title
Supplementation with curcumin versus placebo treatment to lower blood glucose in diabetics: a randomised controlled trial

Acronym
CD

Study objectives
The function of curcumin in lowering blood glucose in diabetic patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee of Public Health College, Harbin Medical University, approved on the 25th June 2009 (ref: 003)

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Diabetes mellitus

Interventions
We determine glucose and insulin with related blood indicators in a hospital. The drug name is Curcumin Qingtang tablet. The dosage given is 2.0 g/60 kg BW/d, equivalent Curcumin 300 mg /kg, take this drug orally for a month.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Curcumin

Primary outcome(s)
Amended as of 21/09/2010:
1. Lipids (triglycerides [TG], total cholestrol [TC], low-density liporotein cholesterol [LDL-C], high-density lipoprotein cholesterol [HDL-C])
2. Free fatty acids (FFAs)
3. Lipoprotein lipase (LPL)
4. Adipocyte fatty acid-binding protein (AFABP)
5. Liver ultrasonography
6. HbA1c
7. Apolipoproteins (ApoA1/ApoB)
8. Triacylglycerol

9. Cholesterol
10. 2-hour post-prandial glucose
11. Homeostasis model assessment - insulin resistance (HOMA-IR)

Initial information at time of registration:
1. Glucose
2. Insulin

Key secondary outcome(s)
Amended as of 21/09/2010:
1. Age
2. Body mass index (BMI)
3. Diabetes duration
4. Cigarette use
5. Physical activity level
6. Food Frequency Questionnaire (FFQ)

Initial information at time of registration:
1. Red blood cell
2. White blood cell
3. Haemoglobin
4. Total protein
5. Albumin
6. Urea nitrogen
7. Creatinine
8. Alanine transaminase
9. Aspartate transaminase
10. Platelet count
11. Height
12. Weight
13. Waist circumference
14. Hip circumference
15. Blood pressure

Completion date
30/07/2009

Eligibility

Key inclusion criteria
1. Type 2 diabetes mellitus; the condition of patients are stable
2. Fasting blood glucose greater than or equal to 7.8 mmol/L or postprandial blood glucose greater than or equal to 11.1 mmol/L
3. Aged 18 - 65 years, both male and female

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Type I diabetes
2. Pregnant or lactating women, or allergic to the tested samples
3. Have history of liver, kidney, hypertension, mental illness, taking other hypoglycaemics
4. People are uncooperative
5. Have diabetic ketosis, acidosis and infection in recent 3 months
6. Taking correlated medications which could potentially influence the purpose of this study
7. Failing to take drugs or the information is incomplete

Date of first enrolment
01/05/2009

Date of final enrolment
30/07/2009

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
Research organisation

Funder Name
Amended as of 21/09/2010:

Funder Name
National Natural Science Foundation of China (NSFC) (China) and Canadian Institutes of Health Research (CIHR) (Canada) - China-Canada Joint Health Research Initiative (ref: 30810107)

Funder Name
Initial information at time of registration:

Funder Name
Development of Health Foods (China)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration