A study of supplementation with Curcumin to Diabetics

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

Contact name Prof Sun Changhao

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 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)

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 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 measure

Amended as of 21/09/2010:

1. Lipids (triglycerides [TG], total cholestrol [TC], low-density liporotein cholesterol [LDL-C], highdensity 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

Secondary outcome measures

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

Overall study start date

01/05/2009

Completion date 30/07/2009

Eligibility

Key inclusion criteria

Type 2 diabetes mellitus; the condition of patients are stable
 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
 Aged 18 - 65 years, both male and female

Participant type(s) Patient

Age group Adult

Lower age limit 18 Years

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Sex Both

Target number of participants 100

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)

Sponsor details

c/o Changhao Sun 157 Baojian Road Nangang District Harbin China 150081 +86 (0)451 87502801 sun2002changhao@yahoo.com

Sponsor type

University/education

Website

http://yxzy.hrbmu.edu.cn/gongwei/english/home.asp?id=400

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

Publication and dissemination plan Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary Not provided at time of registration