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Research on the comprehensive therapy for impaired glucose tolerance (IGT) by traditional Chinese medicine

Submission date	Recruitment status	[ ] Prospectively registered
10/06/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/07/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
03/05/2011	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2006BAI04A04-02

Study information

Scientific Title

Study objectives
Some randomised controlled trials have specifically examined the effects of lifestyle and drug interventions on the prevention of type 2 diabetes. The aim of our randomised controlled trial is to study the effects of traditional Chinese medicine on the prevention of type 2 diabetes, which has not yet been carried out to date.

Hypothesis:
Lifestyle intervention combined with traditional Chinese medicine could reverse IGT to normal, and decrease associated risks of type 2 diabetes and cardiovascular diseases.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee, Guang'an Men Hospital, China Academy of Chinese Medical Sciences. on 28/02/2008

Study design
Randomised double-blind placebo-controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Patient information can be found at: http://www.gamh.com.cn/tangniaobing/zqtys.htm (in Chinese)

Health condition(s) or problem(s) studied
Type 2 diabetes/ cardiovascular diseases

Interventions
1. Traditional Chinese medicine Tian-qi Jiang-tang Capsule™, 5 capsules three times a day, combined with lifestyle interventions
2. Placebo combined with lifestyle interventions

Lifestyle interventions: Diabetes experts will give a talk on physical exercise and diet to a group of participants at baseline, lasting about 45 minutes. In addition, the researchers (usually doctors) will give advice to the participants individually at baseline and every 3 months. We will examine the results of the lifestyle interventions every 3 month by questionnaires, and will adjust the individual advice according to the results of the questionnaires.

Total duration of interventions: 3 years

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Blood glucose (FPG and 2hPG of OGTT) at baseline, and every 3 months during intervention (3 years) and follow-up (6 months).

Secondary outcome measures
Risk of cardiovascular disease, assessed by the following:
1. Blood lipid, assessed at baseline, 6, 12, 18, 24, 30 and 36 months
2. Blood pressure, measured at baseline and then every 3 months during the intervention (3 years) and follow-up (6 months)
3. BMI, measured every 3 months during the intervention (3 years) and follow-up (6 months)
4. Electrocardiogram (ECG), carried out every 6 months during the intervention (3 years)

The following will be assessed in a sub-group of approximately 500 participants:
1. HbA1c, assessed every 6 months during the intervention (3 years)
2. Urinary albumin excretion rate (UAER), assessed at baseline, at 3, 6, 12 and 36 months
3. High-sensitivity C-reactive protein (hs-CRP) baseline, 12 and 36 months
4. Adiponection, baseline, 12 and 36 months
5. OGTT:
5.1. At baseline (0 hour), assessed at baseline and every 3 month during the intervention (3 years) and follow-up (6 months)
5.2. 0.5 hours, assessed at baseline, 6, 12, 24 and 36 months
5.3. 1 hour, assessed at baseline, 12 and 36 months
5.4. 2 hours, assessed at baseline and then every 3 months during the intervention (3 years) and follow-up (6 months)
6. Insulin level:
6.1. Baseline insulin level, measured at baseline (0 month) and every three months until 12 months, and then 24 and 36 months
6.2. Insulin level at 0.5 hours, measured at baseline (0 month) and every three months until 12 months, and then 24 and 36 months
6.3. Insulin level at 1 hour, measured at baseline (0 month), 12 and 36 months
6.4. Insulin level at 2 hours, measured at baseline, every three months until 12 months, and then 24 and 36 months

Note: We will choose the participants who will likely to be compliant for the sub-group study.

Overall study start date
01/03/2008

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. Both males and females
2. 25 =< age <=70
3. Intravenous plasma glucose: Fasting plasma glucose (FPG) <7.0 mmol/L and 2-hour plasma glucose (2hPG) of oral glucose tolerance test (OGTT) <11.1 mmol/L, >=7.8 mmol/L
4. Deficiency of both qi and yin syndromes accompanied by heat
5. Taking no medicine for treatment of IGT
6. 18.5 kg/m2 < body mass index (BMI) <30 kg/m2
7. Voluntariness, and signed letter of consent
8. Those who do not take part in any other trails within 3 months

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
2,000 (As of 03/05/2011; 804 particpated)

Key exclusion criteria
1. Acute cardiovascular disease and myocardial infarction within 6 months
2. Proliferative retinopathy that needs to be treated by laser
3. Not compliant
4. Mental disease
5. Pregnant or lactating women; women without contraception
6. Allergic to any traditional chinese medicine
7. Co-morbid with other endocrine disease or serious protopathy
8. Systolic blood pressure (SBP) >= 160 mmHg, diastolic blood pressure (DBP) >= 100 mmHg and secondary hypertension
9. Cholesterol (CHO) >= 6.22 mmol/L(240 mg/dl) or low density lipoprotein (LDL) >= 4.14 mmol/L (160 mg/dl)
10. Patients who are treated by other hypoglycemic drug

Date of first enrolment
01/03/2008

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
China

Study participating centre
Guang'an Men Hospital
Beijing
China
100053

Sponsor information

Organisation
Ministry of Science and Technology of the People's Republic of China (China)

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Sponsor type
Government

Website
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https://ror.org/027s68j25

Funder(s)

Funder type
Government

Funder Name
Ministry of Science and Technology of the People's Republic of China, National Key Technology R&D Programme (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