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The efficacy and safety of a Korean traditional medicine named 'Taeumjowi-tang' on obese patients

Submission date	Recruitment status	[_] Prospectively registered
24/03/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/04/2010	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
05/09/2012	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
CCRG_08_02

Study information

Scientific Title
A double blind, randomised, multicentre, placebo-controlled trial to evaluate the efficacy and safety of TJ001 on obese patients

Study objectives
'Taeumjowi-tang' is more effective than placebo on obese patients

Please note as of 14/12/2012 anticipated end date has been modified from 30/06/2011 to 30/06/2012.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Institutional Review Board of the Catholic University of Korea Seoul St. Mary's Hospital approved on the 24th of February 2009 (ref: KC09MNME0032)
2. Institutional Review Board of the Dongguk University Ilsan Oriental Hospital approved on the 5th of February 2009 (ref: SR-09)
3. Institutional Review Board of the Semyung University Oriental Medicine Hospital approved on the 27th of March 2009 (ref: 2008-03)
4. Institutional Review Board of the Kyungwon Gil Oriental Medical Hospital approved on the 7th of August 2008 (ref: 08-101)

Study design
Multicentre double blind randomised placebo 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
Obesity

Interventions
1. Treatment group: TJ001 (Taeumjowi-tang) 7g, 3 times/day, 4 weeks (28 days)/visit, total 12 weeks (visit 2 - visit 5)
2. Control group: placebo 7g, 3 times/day, 4 weeks (28 days)/visit, total 12 weeks (visit 2 - visit 5)

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Weight reduction (over 5%), measured at baseline and 12 weeks

Secondary outcome measures
1. Weight reduction, measured at baseline, 4, 8 and 12 weeks
2. Lipid profile and C-reactive protein (CRP), measured at baseline and 12 weeks
3. Blood pressure, measured at baseline and 12 weeks
4. Blood glucose, measured at baseline and 12 weeks
5. Waist/hip ratio, measured at baseline, 4, 8 and 12 weeks
6. Waist circumference, measured at baseline, 4, 8 and 12 weeks
7. Abdominal computed tomography, measured at baseline and 12 weeks
8. Korean Obesity-related Quality of Life (QoL) scale, measured at baseline and 12 weeks
9. Korean version of Eating Attitudes Test-26, measured at baseline and 12 weeks

Overall study start date
08/04/2009

Completion date
30/06/2012

Eligibility

Key inclusion criteria
1. Men or women aged 18-65 years old
2. Patients applying to one of the followings
2.1. BMI 30kg/m2 or over
2.2. BMI 27-30kg/m2 with hypertension in a proper treatment and blood pressure controlled 95-145mmHg
2.3. BMI 27-30kg/m2 with non-insulin-dependent diabetes mellitus and fasting blood glucose < 7.8mmol/L(140mg/dL)
2.4. BMI 27-30kg/m2 with hyperlipidemia in a proper treatment
2.5. BMI 27-30kg/m2 and Total cholesterol 236mg/dL or over or Triglyceride 150mg/dL or over at screening
3. Agreed to low-calorie diet during the trial
4. Written informed consent of the trial
5. Written informed consent of the genetic test

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
A total of 104 patients

Key exclusion criteria
1. Endocrine disease such as hypothyroidism, Cushing's syndrome, etc.
2. Heart disease (heart failure, angina pectoris, myocardial infarction)
3. Uncontrolled hypertension (SBP > 145 mmHg or DBP > 95 mmHg)
4. Malignant tumour or lung disease
5. Cholelithiasis
6. Severe renal disability (SCr > 2.0 mg/dL)
7. Severe liver disability (2.5 fold of normal high range value on Alanine Aminotransferase [ALT], Aspatate Aminotransferase [AST], alkaline phosphatase)
8. Non-insulin-dependent diabetes mellitus and fasting blood sugar 7.8mmol/L (140 mg/dL) or over
9. Narrow angle glaucoma
10. History or existence of neurological or psychological disease (schizophrenia, epilepsy, alcoholism, drug addiction, anorexia, bulimia, etc.)
11. History of stroke or temporary ischemic cardioplegia
12. History or existence of eating disorder such as anorexia nervosa or bulimia nervosa, etc.
13. Use of medication that could have effect on weight within last 3 months (appetite suppressant, laxative, oral steroid, thyroid hormone, amphetamine, cyproheptadine, phenothiazine or medication having effect on absorption, metabolism, excretion)
14. Use of B-blocker or diuretic as hypertension medication within last 3 months
15. Use of medication for central nervous system or central active weight reduction medication
16. Forbidden treatment (Insulin, hypoglycemic agent, antidepressant, antiserotonin agent, barbiturate, antipsychotic, medication concerns of abuse)
17. Difficult to measure anthropometric dimensions because of anatomical change such as resection
18. Surgical history for weight reduction; bariatric surgery, etc.
19. Unable to follow instructions of the trial as judged by investigator
20. Women who were pregnant, lactating, planning a pregnancy or women of childbearing age who do not agree to proper contraception (birth-control pill, hormone implant, IUD, spermicide, condom, abstinence, etc.) (Women of childbearing age indicate within 2 years of menopause who did not receive hysterectomy, bilateral tubal ligation, bilateral oophorectomy, etc.)
21. Use of other investigational product within last 1 month
22. Reduction over 10% of the previous weight within 6 months
23. Decided to stop smoking within last 3 months; however, keeping irregular smoking habit

Date of first enrolment

08/04/2009

Date of final enrolment
30/06/2012

Locations

Countries of recruitment
Korea, South

Study participating centre
Department of Preventive Medicine
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Sponsor information

Organisation
Korea Health Industry Development Institute (South Korea)

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Sponsor type
Research organisation

Website
http://www.khidi.or.kr

ROR
https://ror.org/00fdzyk40

Funder(s)

Funder type
Research organisation

Funder Name
Korea Health Industry Development Institute (South Korea)

Alternative Name(s)
KHIDI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Korea, South

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	07/04/2012		Yes	No