ISRCTN13677132 https://doi.org/10.1186/ISRCTN13677132

Investigating the effects of the herbal medicine Taeeumjowui-tang on obesity and metabolic syndrome risk factors

Submission date
14/01/2019

Recruitment status
No longer recruiting

Registration date
30/01/2019

Overall study status
Completed

Last Edited
20/09/2021

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Sasang constitutional medicine (SCM) is a unique traditional Korean therapeutic alternative form of medicine. SCM classified individuals into 4 types: Taeyang, Soyang. Taeeum, and Soeum. Clinical diagnosis and treatment are done according to the constitution. Taeeum type is considered as a constitution that is easily affected by metabolic syndrome including obesity.

Taeeumjowui-tang is the herbal medicine widely used for taeeum type people. Recent studies have been continued to investigate its effects on obesity, lipid metabolism, metabolic syndrome, and hepatotoxicity.
The aim of this study is to estimate the effect and safety of Taeeumjowui-tang on overweight and obesity with metabolic syndrome risk factors in Taeeum-in constitution diagnosed by SCAT (Sasang Constitutional Analysis Tool) after 12-week oral administration.

Who can participate?
Overweight and obese Taeeum-in (Taeeum type people) with metabolic syndrome risk factors.

What does the study involve?
This is a one-group, pretest-posttest design trial. All participants will be receiving 5g Taeeumjowui-tang, administered 3 times daily, 2 packs at a time.

What are the possible benefits and risks of participating?
Participants will have the chance to be diagnosed by SCAT (Sasang constitutional Analysis Tool) and classified into four constitutions. Potential benefits include improvements in BMI and metabolic syndrome risk factors. Potential side effects include insomnia, excessive sweating, tachycardia, frequent urination, general weakness, mental excitement, anorexia, stomach discomfort, nausea, vomiting, diarrhea, and dysuria.

Where is the study run from?
Cheonan Oriental Hospital and Dunsan Oriental Hospital.

When is the study starting and how long is it expected to run for?
The trial is expected to start on 01/02/2019, and end on 31/05/2020

Who is funding the study?
This work was supported by the National Research Foundation of Korea(NRF) grant funded by the Korea government(MSIT) (Grant Mo.: 2015M3A9B6028311).

Who is the main contact?
The main contact is Dr. Teak-Won Ahn, twahn@dju.ac.kr.

Contact information

Type(s)
Public

Contact name
Mr Taek-Won Ahn

ORCID ID
http://orcid.org/0000-0002-5716-540X

Contact details
4, Notaesan-ro, Seobuk-gu, Cheonan-si, Chungcheongnam-do, Republic of Korea
Cheonan
Korea, South
31099
+82, 041-521-7538
twahn@dju.ac.kr

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MSTE-SCAT-1802

Study information

Scientific Title
The effect of Taeeumjowui-tang on overweight or obesity with metabolic syndrome risk factors in Taeeum-in constitution diagnosed by SCAT (Sasang constitutional Analysis Tool): a non-randomised trial

Study objectives
Recent studies have been continued to investigate the effects of Taeeumjowui-tang on obesity, lipid metabolism, metabolic syndrome, and hepatotoxicity. In Sasang constitutional medicine

(SCM), Taeeumjowui-tang is the herbal medicine best suited to taeeum type people. The objective of this study is to investigate whether Taeeumjowui-tang could influence obesity and metabolic syndrome risk factors.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional review board of Cheonan Oriental Hospital of Daejeon University, 21/12/2018, ref. DJUMC-2018-DR-01
Institutional review board of Dunsan Oriental Hospital of Daejeon University, 03/12/2018, ref. DJDSKH-18-DR-24

Study design
Interventional, non-randomised

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Metabolic syndrome

Interventions
1. Generic drug name : Taeeumjowui-tang
2. The dosage given, the method and frequency of administration : total 30 grams daily, orally administered. (3 times daily, 2 packs at a time. One pack contains 5 grams of Taeeumjowui-tang.)
3. The total duration of treatment : 12 weeks
4. Follow-up: the subjects will have 5 visits: visit 1 screening, visit 2 enrollment, and 3 other visits 4, 8, 12 weeks after visit 2, respectively. (±5 days of error range). On every visit, anthropometric and vital sign data will be collected, and clinical laboratory test will be carried on. Calculation of Body Mass Index (BMI) will also be done on every visit. Any drug combinations and adverse events will be checked on visit 3~5. Clinical drug compliance will be checked on visit 3~5, and on visit 5, the total compliance will be assessed.

Intervention Type
Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)
Taeeumjowui-tang

Primary outcome measure
Body Mass Index (BMI) will be measured at baseline (visit 2) and 12 weeks later (visit 5)

Secondary outcome measures
1. Improvement in the number of metabolic syndrome risk factors according to the metabolic syndrome criteria (NCEP-ATPIII, 2006 Defining Abdominal Obesity in the Korean Population, Korean Society for the Study of Obesity). Metabolic syndrome is diagnosed when three or more of the following criteria are met.
1.1. Waist circumberence: men ≥ 90 cm, women ≥ 85 cm.
1.2. High fasting glucose: ≥ 100 mg/dL
1.3. Hypertriglyceridemia: ≥ 150 mg/dL
1.4. Low HDL-chol. : men <40 mg/dL , women <50 mg/dL
1.5. High blood pressure: ≥ 130/85 mmHg
2. Dyslipidemia will be determined using changes in triglyceride, total cholesterol, HDL-cholesterol and LDL-cholesterol at baseline, 4 weeks, 8 weeks, and 12 weeks.
3. Changes in blood pressure will be determined by measuring blood pressure (SBP, DBP) at baseline, 4 weeks, 8 weeks, and 12 weeks.
4. Blood sugar will be measured using:
4.1. Changes in FBS (IFG), insulin NS free fatty acid at baseline, 4 weeks, 8 weeks, and 12 weeks.
4.2. Changes in HbA1c at baseline, 8 weeks, and 12 weeks.
5. Obesity factors will be measured using:
5.1. Changes in BMI at baseline, 4 weeks, and 8 weeks.
5.2. Changes in waist circumference at baseline, 4 weeks, 8 weeks, and 12 weeks.
6. Collecting oriental medical information:
6.1. Facial color measurement, voice measurement, body measurement, and questionnaire at visit 5.
6.2. 3D facial measurement at visit 1 and 5.
6.3. Tongue diagnosis, body temperature (Digital Infrared Thermal Imaging) measurement at visit 2 and 5.
7. The changes in glucose metabolism and metabolic syndrome risk factors will be measured using the oral glucose tolerance test (OGTT) on 30 subjects whose fasting blood glucose level is 110 mg/dl or more, and who are not taking diabetes medication.

Overall study start date
01/04/2018

Completion date
31/05/2020

Eligibility

Key inclusion criteria
1. Aged between 19 and 64.
2. Diagnosed by SCAT (Sasang Constitutional Analysis Tool) as a Taeum type person (Taeum-in).
3. BMI of 23 or more
4. Meet the criteria of waist circumference, and one or more other metabolic syndrome criteria.

5. Blood pressure, diabetes, and hyperlipidemia are controlled stably so do not need additional medical prescriptions.
6. Able to communicate with researchers and are able to follow the test compliance.

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
206

Total final enrolment
206

Key exclusion criteria
1. Meet the following criteria
1.1. HbA1c 8.5% or more
1.2. Fasting triglyceride : TG ≥ 400
1.3. LDL-chol. ≥ 190
1.4. Blood pressure ≥160/100mmHg
2. History of severe renal impairment (renal failure, nephrotic syndrome, glomerular disease), dialysis history, or Cr level more than twice the normal upper limit.
3. History of severe liver disease (cirrhosis, liver cancer), or AST or ALT greater than 2.5 times the normal level.
4. Acute phase or urgent angina pectoris, myocardial infarction, stroke, cardiac or cerebrovascular disease.
5. Gastrointestinal problems(anorexia, nausea, vomiting, etc.) unlikely to be able to participate under the researcher’s judgement.
6. Those who have participated in other interventional clinical trials within the last 3 months.
7) Artificial weight loss of more than 10% of the total weight within 6 weeks.
8) Those with neuropsychiatric disorders.
9) Those with excessive alcohol consumption (more than 14 bottles per week)
10) Allergic to test drug ingredients
11) Those who plan to participate in other clinical trials during the course of this trial.
12) Currently taking medication for hyperthyroidism, or TSH level more than 1.5 times the normal upper limit.
13. Diagnosed with malignant tumor or received chemotherapy within 5 years.
14. Those who have taken the following medications within 3 months:
14.1. Ephedrine
14.2. MAO inhibitors
14.3. Thyroid medications (thyroxine, lyothionine)
14.4. Catecholamines (epinephrine, isoprenaline)
14.5. Xanthines (theophylline, dipropyline).
15. Changes in medical prescriptions for blood pressure, diabetes, hyperlipidemia, obesity within 3 months.
16. Other serious medical conditions or symptoms unlikely to be able to participate under the

researcher’s judgement.
17. Hidrosis
18. Excessive weakness, or in the aftermath of a disease.
19. Severe urinary disorders
20. Genetic problems such has galactose intolerance, Lapp lactase deficiency, or glucose-galactose malabsorption.
21. Those who are expected to have dietary changes during the clinical trial
22. Pregnant or the possibility of pregnancy, or nursing mother.
23. Those who have a history of elevated blood glucose by taking ephedrine
24. Those who have taken drugs that can affect body weight such as appetite suppressants, laxatives (without prescription) or oral steroids, thyroid hormones, amphetamines, ciproheptadine, phenodiazines, or drugs that affect absorption or metabolism within 3 months.
25. Those who have undergone surgical surgery for weight loss such as gastroplasty.

Date of first enrolment
01/02/2019

Date of final enrolment
01/03/2020

Locations

Countries of recruitment
Korea, South

Study participating centre
Cheonan Oriental Hospital of Daejeon University
4, Notaesan-ro, Seobuk-gu
Cheonan-si
Korea, South
31099

Study participating centre
Dunsan Oriental Hospital of Daejeon University
75, Daedeok-daero 176 beon-gil,
Seo-gu
Daejeon
Korea, South
35235

Sponsor information

Organisation
Cheonan Oriental Hospital of Daejeon University

Sponsor details
4, Notaesan-ro, Seobuk-gu, Cheonan-si, Chungcheongnam-do, Republic of Korea
Cheonan
Korea, South
31099
+82, 041-521-7000
twahn@dju.ac.kr

Sponsor type
Hospital/treatment centre

Website
https://www.djuca.or.kr/index.html

ROR
https://ror.org/05vc01a67

Funder(s)

Funder type
Government

Funder Name
Korea government (Ministry of Science and ICT)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/05/2021

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/09/2021	20/09/2021	Yes	No