

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

Submission date 14/01/2019	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/01/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 20/09/2021	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> 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, Taeum, and Soeum. Clinical diagnosis and treatment are done according to the constitution. Taeum type is considered as a constitution that is easily affected by metabolic syndrome including obesity.

Taeumjowui-tang is the herbal medicine widely used for taeum 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 Taeumjowui-tang on overweight and obesity with metabolic syndrome risk factors in Taeum-in constitution diagnosed by SCAT (Sasang Constitutional Analysis Tool) after 12-week oral administration.

Who can participate?

Overweight and obese Taeum-in (Taeum 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 Taeumjowui-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

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Additional identifiers

Protocol serial number

MSTE-SCAT-1802

Study information

Scientific Title

The effect of Taeumjowui-tang on overweight or obesity with metabolic syndrome risk factors in Taeum-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 Taeumjowui-tang on obesity, lipid metabolism, metabolic syndrome, and hepatotoxicity. In Sasang constitutional medicine (SCM), Taeumjowui-tang is the herbal medicine best suited to taeum type people. The objective of this study is to investigate whether Taeumjowui-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. DJJMC-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

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Metabolic syndrome

Interventions

1. Generic drug name : Taeumjowui-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 Taeumjowui-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)

Taeumjowui-tang

Primary outcome(s)

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

Key secondary outcome(s)

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 circumference: 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: \geq 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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

206

Key exclusion criteria

1. Meet the following criteria

1.1. HbA1c 8.5% or more

1.2. Fasting triglyceride : TG \geq 400

1.3. LDL-chol. \geq 190

1.4. Blood pressure \geq 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 as 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

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Study participating centre

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Korea, South

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Sponsor information

Organisation

Cheonan Oriental Hospital of Daejeon University

ROR

<https://ror.org/05vc01a67>

Funder(s)

Funder type

Government

Funder Name

Korea government (Ministry of Science and ICT)

Results and Publications

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