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A clinical study of bojungikgitang and banhabaekchulchonmatang in adult tinnitus patients

Submission date 25/05/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 05/06/2009	**Overall study status** Completed	
Last Edited 29/07/2010	**Condition category** Ear, Nose and Throat	

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
B08-0045-AM0829-08N1-00010A

Study information

Scientific Title
A clinical study of bojungikgitang and banhabaekchulchonmatang in adult tinnitus patients: a randomised, double-blind, three-arm, placebo-controlled trial

Study objectives
This study is aimed to evaluate the efficacy and safety of bojungikgitang and banhabaekchulchonmatang in adult tinnitus patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wonkwang University Oriental Medical Center Ethics Committee gave approval on the 25th February 2009

Study design
Randomised phase III double-blind three-arm 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
Tinnitus

Interventions
This study is a randomised, double-blind, placebo-controlled study. Participants will receive bojungikgitang, banhabaekchulchonmatang, or a placebo-drug for 8 weeks. Oral administration occurs according to the following statements:
1. Patients in group 1 receive bojungikgitang and instructions on how to make a tea; they take a packet of the medicine (12.52 g) with tepid water for three times a day after meal
2. Patients in group 2 receive banhabaekchulchonmatang and instructions on how to make a tea; they take a packet of the medicine (12.52 g) with tepid water for three times a day after meal
3. Patients in group 3 receive the placebo medicine (powdered extract), used in the same way as with group 1 and 2

The total duration of all arms is 11 weeks. Timepoints are as follows:
Visit 1: screening
Visit 2: treatment initiation, participants will receive bojungikgitang, banhabaekchulchonmatang, or a placebo-drug for 8 weeks
Visit 3: 4 weeks later of first medication, follow-up
Visit 4: 8 weeks later of first medication, follow-up and treatment finish
Visit 5: 10 weeks later of first medication, follow-up

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Bojungikgitang, banhabaekchulchonmatang

Primary outcome measure
Efficacy:
Tinnitus Handicap Inventory (THI): the purpose of this questionnaire is to identify difficulties that may be experienced because of tinnitus:
1.1. F: Functional subscale (11 factors)
1.2. E: Emotional subscale (9 factors)
1.3. C: Catastrophic subscale (5 factors)
Measured at baseline (1 week before treatment initiation), 4 weeks later of the first medication, 8 weeks later of the first medication, follow up (2 weeks later of treatment period)

Safety:
1. Complete blood cell count, erythrocyte sedimentation rate (ESR)
2. Blood chemistry
3. Urine analysis
4. Chest antero-posterior (PA) film
Measured at baseline, 8 weeks later of the first medication

5. Brain computed tomography (CT)
6. Otologic examination
Measured at baseline

7. Vital signs; measured at baseline, treatment initiation, 4 weeks later of the first medication, 8 weeks later of the first medication

Secondary outcome measures
Efficacy:
1. Acoustic Examination (AE)
2. Visual Analogue Scale (VAS)
Measured at baseline (1 week before treatment initiation), 4 weeks later of the first medication, 8 weeks later of the first medication, follow up (2 weeks later of treatment period)

3. EQ-5D
4. Health Utilities Index Mark 3 (HUI3)
Measured at baseline, 8 weeks later of the first medication, follow up

Overall study start date
01/03/2009

Completion date
30/09/2009

Eligibility

Key inclusion criteria
1. Age greater than 19 years, either sex
2. Typical conditions of intermittent or continuous tinnitus
2.1. The duration of more than 3 months
2.2. Involuntary perception of the concept of a sound without the presence of an external source
3. Agreed not to receive another treatment during the clinical trial period
4. Written and informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Receiving other forms of tinnitus treatments
2. Underlying disease or history:
2.1. Otitis media
2.2. Acoustic tumour
2.3. Intracranial lesion
2.4. Inner ear malformation
2.5. Head trauma
2.6. Ototoxic drug medication, etc.
3. Women in pregnacy and lactation or without contraception
4. Other clinical trial within the last 1 month
5. Auditory surgery, a major surgery or a blood transfusion within the last 1 month
6. Hypersensitiveness or allergy of drugs
7. Disease which can affect the absorption of drugs or disordered digestion after surgery related to the disease
8. History of neuropsychitric abnormality:
8.1. Manic-depression
8.2. Schizophrenia
8.3. Alcoholism
8.4. Drug addiction, etc.
9. Cannot understand a written consent or follow this study:
9.1. Mental retardation

9.2. Mental or emotional problems
10. Judged by expert that they are inappropriate to participate in this study

Date of first enrolment
01/03/2009

Date of final enrolment
30/09/2009

Locations

Countries of recruitment
Korea, South

Study participating centre
Wonkwang University Oriental Medical Center
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Sponsor information

Organisation
Korea Health Industry Development Institute (KHIDI) (South Korea)

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Sponsor type
Research organisation

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ROR
https://ror.org/00fdzyk40

Funder(s)

Funder type
Research organisation

Funder Name
Korea Health Industry Development Institute (KHIDI) (South Korea) - The 2008 Traditional Korean Medicine Research and Development Project

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	28/03/2010		Yes	No