ISRCTN58013563 https://doi.org/10.1186/ISRCTN58013563

Effects of acupuncture on heart rate variability in adult tinnitus patients

Submission date	Recruitment status	[X] Prospectively registered
25/06/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/09/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/02/2019	Ear, Nose and Throat	

Plain English summary of protocol

Current plain English summary as of 04/02/2019:
Background and study aims
Tinnitus is the term for hearing sounds that come from inside your body rather than from an outside source, often described as "ringing in the ears". Severe tinnitus is associated with anxiety and depression. Hand acupuncture is a system of acupuncture in which the hand is considered to be a representation of the entire body and stimulation of specific points on the hand with needles or lasers is used to obtain effects in distant areas of the body. The aim of this study is to evaluate the effect of acupuncture on ANS reactivity in patients with chronic tinnitus.

Who can participate?
Patients aged 18-65 with tinnitus

What does the study involve?
Participants are randomly allocated to be treated with deep acupuncture or shallow acupuncture. Treatment is conducted over a period of 3 weeks, at a frequency of two sessions per week. No additional treatment is allowed. Tinnitus severity and adverse events are assessed in both groups.

What are the possible benefits and risks of participating?
It is possible that acupuncture will help improve tinnitus symptoms but we cannot say this for certain until we have completed this and further studies. Adverse events may include discomfort or bruising at the sites of needle insertion, nausea, or feeling faint.

Where is the study run from?
Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University (China)

When is the study starting and how long is it expected to run for?
October 2012 to October 2013

Who is funding the study?
Beijing health system high-level health technology talent cultivation plan (China)

Who is the main contact?
Dr Cunzhi Liu

Previous plain English summary:
Background and study aims
Tinnitus is the term for hearing sounds that come from inside your body rather than from an outside source, often described as "ringing in the ears". Severe tinnitus is associated with anxiety and depression. Hand acupuncture is a system of acupuncture in which the hand is considered to be a representation of the entire body and stimulation of specific points on the hand with needles or lasers is used to obtain effects in distant areas of the body. The aim of this study is to test whether acupuncture can be used to treat tinnitus by comparing the effect of needle and laser acupuncture in adult tinnitus patients.

Who can participate?
Patients aged 18-65 with tinnitus

What does the study involve?
Participants are randomly allocated to be treated with acupuncture using either needles or lasers. Treatment is conducted over a period of 3 weeks, at a frequency of two sessions per week. No additional treatment is allowed. Tinnitus severity and adverse events are assessed in both groups.

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Dr Cunzhi Liu

Contact information

Type(s)
Scientific

Contact name
Dr Cunzhi Liu

Contact details
23 Meishuguanhou Street
Dongcheng District
Beijing

China
100010

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Current scientific title as of 04/02/2019:
Effects of deep acupuncture versus shallow acupuncture on heart rate variability in adult tinnitus patients: an exploratory study

Previous scientific title:
Effects of hand acupuncture and shallow acupuncture on heart rate variability in adult tinnitus patients: a randomized controlled trial

Study objectives
Current study hypothesis as of 04/02/2019:
This study is aimed to compare the effect of deep acupuncture versus shallow acupuncture on heart rate variability in adult tinnitus patients.

Previous study hypothesis:
This study is aimed to compare the effect of hand acupuncture and shallow acupuncture on heart rate variability in adult tinnitus patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Beijing Hospital of Traditional Chinese Medicine & Capital Medical University, 28/02/ 2012

Study design
Randomised 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
Current interventions as of 04/02/2019:
30 tinnitus patients are randomized to receive deep acupuncture or shallow acupuncture for 3 weeks (twice per week).

Patients are stimulated by 5 main acupoints: Baihui (Du-20), Shenting (Du-24), Tinghui (GB-2), Waiguan (SJ-5), Zulinqi (GB-41). The acupoints are stimulated by the true needles or the laser-needles for 20 minutes per session.

Previous interventions:
30 tinnitus patients are randomized to receive hand acupuncture or shallow acupuncture for 3 weeks (twice per week).

Patients are stimulated by 5 main acupoints: Baihui (Du-20), Shenting (Du-24), Tinghui (GB-2), Waiguan (SJ-5), Zulinqi (GB-41). The acupoints are stimulated by the true needles or the laser-needles for 20 minutes per session.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Heart rate variability (HRV), measured before and after the first acupuncture session, as well as 3 weeks after the whole acupuncture treatment.

Secondary outcome measures
1. Change of tinnitus severity according to the tinnitus questionnaire of Tinnitus Handicap Inventory (THI):
1.1. F: Functional subscale (11 factors)
1.2. E: Emotional subscale (9 factors)
1.3. C: Catastrophic subscale (5 factors)
Each question of the THI can be answered by the patient with either often (2 points), sometimes (1 point) or never (0 points) with a maximum total score of 100 indicating most severe suffering from tinnitus. The assessment was before and after the first acupuncture session, as well as 3 weeks after the whole acupuncture treatment.
2. Participants also reported adverse events they experienced, including discomfort or bruising at the sites of needle insertion, nausea, or feeling faint after each treatment.

Overall study start date
03/10/2012

Completion date
06/10/2013

Eligibility

Key inclusion criteria
1. Typical conditions of unilateral or bilateral tinnitus
2. Age 18-65 years, either sex
3. Tinnitus duration of more than 3 months
4. Not receive any treatment last 1 month
5. Normal language and intelligence ability to answer and fill in the questionnaire
6. Correct understanding of acupuncture, and good compliance to the research observation and evaluation
7. Written and informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Objectivity tinnitus
2. Acute or intermittent tinnitus, history of Meniere disease or tinnitus induced by middle ear /inner ear/small pons Angle tumor
3. Underlying disease or history: otitis media, tympanic membrane perforation, eustachian tube function obstacle
4. Acoustic neuroma, Intracranial damage, inner ear disease or use of any ototoxic drugs
5. Severe dysfunction of heart, kidneys or liver
6. The serious original disease of hematopoietic system or endocrine system
7. Serious aphasia, depression syndrome or mental disease

Date of first enrolment
03/10/2012

Date of final enrolment
06/10/2013

Locations

Countries of recruitment
China

Study participating centre
23 Meishuguanhou Street
Beijing
China
100010

Sponsor information

Organisation
Beijing Municipal Health Bureau (China)

Sponsor details
70 Zaolinqian Sreet
Xuanwu District
Beijing
China
100053

Sponsor type
Government

ROR
https://ror.org/0374a5s68

Funder(s)

Funder type
Government

Funder Name
Beijing Health System (China) - High Level Health Technology Talent Cultivation Plan ref: 2011-3-055

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?
Basic results		04/02/2019	04/02/2019	No	No