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Acupuncture at local and distant points for tinnitus

Submission date	Recruitment status	[_] Prospectively registered
06/04/2012	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/05/2012	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
09/06/2014	Ear, Nose and Throat	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Tinnitus is a term that describes any sound a person can hear from inside their body rather than from an outside source. There is currently no generally accepted explanation of how these phantom sounds come about, and also no effective treatment. Pilot studies have revealed that acupuncture may be used to treat tinnitus. Acupuncture points (acupoints) are locations on the body that are the focus of acupuncture treatment in traditional Chinese medicine. Acupoints located near to the area of the disease (local) and away from the area of the disease (distal) can be needled to treat the disease, and combining these acupoints can make the treatment more effective. The aim of this study is to assess the effects of acupuncture in subjective tinnitus patients.

Who can participate?
Patients aged 18-65 years who have had subjective tinnitus in one or both ears for at least 3 months.

What does the study involve?
Patients will be randomly allocated to one of four treatment groups. Group A will receive acupuncture at local acupoints in combination with distal acupoints. Group B will receive acupuncture at local acupoints in combination with distal non-acupoints (i.e., areas that are not acupoints). Group C will receive acupuncture at local non-acupoints in combination with distal acupoints. Group D will receive acupuncture at local non-acupoints in combination with distal non-acupoints. Participants will receive acupuncture for 4 weeks, at a frequency of two sessions per week. Acupuncture will be performed with sterile needles by a therapist with more than 6 years experience and an acupuncture license from the Ministry of Health of the Peoples Republic of China. No additional treatment will be allowed.

What are the possible benefits and risks of participating?
During the study, you will receive regular check-ups including hearing tests. Acupuncture may help improve your tinnitus but we cannot say this for certain until we have completed this and further research studies.

Where is the study run from?
Acupuncture clinic, 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?
The study started in February 2012 and will run until December 2014.

Who is funding the study?
Beijing Health System (China).

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
2011-3-055

Study information

Scientific Title
Acupuncture at local and distant points for tinnitus: a randomized, blinded, controlled trial

Study objectives
Evaluate the efficacy of acupuncture at local points in combination with distal points in 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

Randomized blinded controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Subjective tinnitus

Interventions
This study is a randomized, single-blind, controlled study. Participants will receive acupuncture at local points in combination with distal points for 4 weeks.

Time points are as follows:
Visit 1: screening
Visit 2: treatment initiation, participants will receive acupuncture for 4 weeks
Visit 3: 4 weeks after first acupuncture, follow-up and treatment finish
Visit 4: 8 weeks after first acupuncture, follow-up

Patients who met the inclusion criteria and none of the exclusion criteria were randomized to one of four treatment groups:
Group A will receive acupuncture at local acupoints in combination with distal acupoints.
Group B will receive acupuncture at local acupoints in combination with distal non-acupoints.
Group C will receive acupuncture at local non-acupoints in combination with distal acupoints.
Group D will receive acupuncture at local non-acupoints in combination with distal non-acupoints.

Treatment will be conducted over a period of 4 weeks, at a frequency of two sessions per week.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Subjective tinnitus loudness and annoyance perception was graded using the Visual Analogue Scale (VAS). The assessment was at baseline (before treatment initiation), 4 weeks after the first acupuncture and 8 weeks after the first acupuncture.

Key secondary outcome(s))
1. Change of tinnitus severity according to the tinnitus questionnaire of the 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 at baseline (before treatment initiation), 4 weeks after the

first acupuncture and 8 weeks after the first acupuncture.
2. Changes of tone and noise parameters of tinnitus, assessed by tinnitus matching (screening versus week 8) at 4 and 8 weeks after the first acupuncture, follow up.
3. Perceived Credibility of acupuncture was evaluated by The Treatment Credibility Scale (TCS) after a 4-week acupuncture session. It is a 5-item questionnaire ranging from 1 (not at all) to 5 (very confident); items were averaged to provide a single treatment credibility score, with high scores reflecting high treatment credibility.
4. To evaluate the adequacy of blinding, we asked participants to rate how certain they were that they had received traditional acupuncture or a new method of acupuncture on a 7-point scale (1 very sure, 7 very uncertain) after 4 weeks of treatment.
Participants also reported adverse events they experienced, including discomfort or bruising at the sites of needle insertion, nausea, or feeling faint after each treatment.

Completion date
31/12/2014

Eligibility

Key inclusion criteria
1. Diagnosis of subjective tinnitus, unilateral or bilateral
2. Age 18-65 years, either sex
3. Tinnitus duration of at least 3 months
4. Agreed not to receive another treatment during the clinical trial period
5. Written and informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Key exclusion criteria
1. Objective tinnitus
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
3. Women in pregnacy and lactation or without contraception
4. History of or evidence of significant brain malformation or neoplasm, head injury, cerebral vascular events, neurodegenerative disorder, blood transfusion affecting the brain or prior brain surgery
5. Inability to correct use of test equipment: unable to cooperate during audiologic examination
6. Patients who cannot communicate reliably with the investigator or who are not likely to cope with the requirements of the trial

Date of first enrolment
03/03/2012

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
China

Study participating centre
23 Meishuguanhou Street
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100010

Sponsor information

Organisation
Beijing Municipal Health Bureau (China)

ROR
https://ror.org/0374a5s68

Funder(s)

Funder type
Government

Funder Name

Results and Publications

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	23/11/2012		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes