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Effectiveness of auriculotherapy for uncontrolled mild hypertension

Submission date
27/07/2012

Recruitment status
No longer recruiting

Registration date
03/08/2012

Overall study status
Completed

Last Edited
17/06/2014

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Patients who are being treated for hypertension (high blood pressure) may not achieve the recommended blood pressure level. Given the limits of drug therapy, we wish to explore non-invasive complementary methods along with conventional medicine for blood pressure control. The aim of this study was to identify an optimal protocol for the administration of auriculotherapy (ear acupuncture) integrated with Western medication for better control of hypertension.

Who can participate?
This study aims to recruit 60 Chinese men or women with uncontrolled mild hypertension.

What does the study involve?
You will receive auriculotherapy on top of your current Western drugs for treating hypertension. You will be randomly allocated to either Group A or Group B. The auriculotherapy used in this study is a method in which seven small magnetic pellets will be applied on specific points of your ear. In addition to this, if you are allocated to Group B you will be asked to press on the pellets three times daily. If you are allocated to Group A you will not press on the pellets. The whole treatment course will be 4 weeks. During this period, you need to come back to the clinic weekly so that the researcher can remove the old pellets and apply new ones. We will apply the pellets to only one side of your ear each time. We will monitor your blood pressure before the treatment course begins and during your weekly visits to the clinic. After the 4-week treatment course, we will also invite you to the clinic at 1 month and 2 months so as to continue monitoring your blood pressure.

What are the possible benefits and risks of participating?
Your may have a better control of your blood pressure arising from this therapy, but this effect may not be guaranteed because of individual response to treatment. For auriculotherapy using magnetic pellets, side effects arising from this therapy are rare. However, abnormal phenomena such as mild dizziness during or after the procedure, or allergic reactions to the skin from the adhesive tape may be possible. Such reactions are immediately reduced once the tape is removed. Nevertheless, you will be closely monitored by the researchers for the occurrence of these adverse reactions.

Where is the study run from?
The study is conducted at the Department of Cardiology, Prince of Wales Hospital, Hong Kong.

When is the study starting and how long is it expected to run for?
This study is expected to begin in October 2007 and is expected to run for 12 months.

Who is funding the study?
The Health Care and Health Services Research Fund, Hong Kong.

Who is the main contact?
Dr Lorna Suen
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Contact information

Type(s)
Scientific

Contact name
Dr Lorna Suen

Contact details
The Hong Kong Polytechnic University
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effectiveness of auriculotherapy for uncontrolled mild hypertension: a pilot randomized trial

Study objectives
1. Auriculotherapy using magnetic pellets has a significant effect on hypertension control
2. Auriculotherapy using magnetic pellets with or without pressing on the acupoints has no significant differences in hypertension control

Ethics approval required
Old ethics approval format

Ethics approval(s)
Joint Chinese University of Hong Kong New Territories East Cluster Clinical Research Ethics Committee, ref: CRE-2006-398

Study design
Two-arm quasi-experimental pilot study

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
Uncontrolled mild hypertension

Interventions
Group A (experimental group):
The participants received an integrative approach (AT without magnetic pellet pressing plus Western medication). The magnetic pellets used in this study contained an average of ~200 gauss /pellet magnetic flux densities, with a diameter of ~0.13 cm. No pellet pressing should take place. The total treatment period was 4 weeks.

Group B (comparison group):
The participants received an integrative approach (AT with magnetic pellet pressing, plus Western medication). Using the same kind of pellets as in Group A, the clients were additionally asked to press the pellets against the acupoints three times daily, with 1 minute for each point until a sensation of distension and warmth was felt. The clients were required to fill out a self-reported therapy compliance daily record to allow the researcher to monitor the degree of compliance in pellet pressing.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Mean Arterial Pressure (MAP) was used as the main outcome measure in this study owing to its clinical and physiological significance in both the representation of perfusion pressure and the effect on the calculation of hemodynamic variables. After a 10-minute rest, the participants blood pressure readings were recorded using the Datascope Electronic Sphygmomanometer at baseline, at weekly visits to the clinic during the 4-week treatment course, and at 1 month and 2 months following the whole course. Datascope is one of the valid blood pressure measuring devices recently recommended by the European Society of Hypertension for clinical use in hospitals.

Secondary outcome measures
Self reported by the participants at the end of the treatment course and included:
1. Frequency of nocturnal polyuria
2. Perceived sleep condition
3. Calmness of mind
4. Appetite

Overall study start date
01/10/2007

Completion date
01/11/2011

Eligibility

Key inclusion criteria
1. Borderline-controlled hypertension was defined in the present study as blood pressure (BP) remaining above 140/90 mmHg even when the patient was on anti-hypertensive therapy in accordance with the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC) guideline.
2. Chinese patients with uncontrolled mild hypertension

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
70

Key exclusion criteria
1. Secondary hypertension
2. Upper limit of BP more than 160/99 mmHg (as a precaution to exclude high-risk cases and to ensure only cases with mild hypertension were recruited)
3. Pacemakers/implanted electrical devices
4. Pregnancy
5. A history of coronary artery disease or stroke, or comorbid illnesses such as diabetes or

chronic kidney disease
6. Regular maintenance medications (apart from anti-hypertensives) which may affect BP
7. Aural injuries or infections

Date of first enrolment
01/10/2007

Date of final enrolment
01/11/2011

Locations

Countries of recruitment
Hong Kong

Study participating centre
The Hong Kong Polytechnic University
-
Hong Kong
-

Sponsor information

Organisation
Food and Health Bureau (Hong Kong)

Sponsor details
c/o Dr Richard A Collins
Government Secretariat
Murray Building
Garden Road
Central, Hong Kong
-
Hong Kong
-

Sponsor type
Government

Website
http://www.fhb.gov.hk/

ROR
https://ror.org/03qh32912

Funder(s)

Funder type
Government

Funder Name
Health Care and Health Services Research Fund (Hong Kong), ref: 05060461

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