

# Effectiveness of auriculotherapy for uncontrolled mild hypertension

<b>Submission date</b> 27/07/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 03/08/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 17/06/2014	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?

You 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

lorna.suen@polyu.edu.hk

## Contact information

### Type(s)

Scientific

### Contact name

Dr Lorna Suen

### Contact details

The Hong Kong Polytechnic University

School of Nursing

HungHom

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Hong Kong

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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

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Hong Kong

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## **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

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Hong Kong

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**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