# The efficacy of acupressure to prevent antituberculosis drugs-induced adverse effects in pulmonary tuberculosis patients

Submission date	Recruitment status	Prospectively registered
29/04/2015	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
02/05/2015	Completed	[X] Results
<b>Last Edited</b> 31/01/2019	Condition category Infections and Infestations	[] Individual participant data
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## Plain English summary of protocol

Background and study aims

Pulmonary tuberculosis (TB) is a curable bacterial infection that affects the lungs. With the development of a standard six-month drug treatment, the focus of TB management has shifted from controlling and curing the disease to increasing the quality of life of patients. However, many patients have adverse drug reactions during treatment, which can affect patients' quality of life and result in failure to complete treatment. Acupressure has been used to treat adverse drug reactions, but further evidence is needed. Therefore, the aim of this study is to find out whether acupressure prevents adverse drug reactions to anti-tuberculosis drugs in pulmonary TB patients.

### Who can participate?

Pulmonary tuberculosis patients aged 20 or over.

### What does the study involve?

Participants will be randomly allocated to either the experimental group or the control group. All participants undergo an acupressure program for 15 minutes per day, five days per week, for four weeks. Acupressure practitioners use their fingers, palms, elbows or feet, or special devices to apply pressure to specific points on the body (acupoints). The experimental group are treated with acupressure on effective acupoints, while the control group are treated with acupressure on non-effective acupoints.

What are the possible benefits and risks of participating?

The possible benefits of participating will be prevention of adverse drug reactions. The risks of participating will be redness and mild pain at the skin after acupressure.

#### Where is the study run from?

Taipei Veterans General Hospital and Taichung Hospital, Ministry of Health and Welfare (Taiwan).

When is the study starting and how long is it expected to run for? From April 2015 to March 2016.

Who is funding the study? Investigator initiated and funded.

Who is the main contact? Chia-Ju Hsieh

# **Contact information**

### Type(s)

**Public** 

#### Contact name

Prof Chia-Ju Hsieh

### **ORCID ID**

http://orcid.org/0000-0002-3332-9844

### Contact details

No 155, Li-Nong St Beitou District Taipei City Taiwan 11221

# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

# Study information

### Scientific Title

The efficacy of acupressure to prevent anti-tuberculosis drugs-induced adverse effects in pulmonary tuberculosis patients: a randomised parallel trial

# **Study objectives**

Acupressure can prevent anti-tuberculosis drug-induced adverse effects in pulmonary tuberculosis patients

# Ethics approval required

Old ethics approval format

Ethics approval(s)

### Institutional Review Board, Taipei Veterans General Hospital

### Study design

Multicentre interventional trial

### Primary study design

Interventional

### Secondary study design

Randomised parallel trial

### Study setting(s)

Home

### Study type(s)

Prevention

### 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

Pulmonary tuberculosis

#### **Interventions**

Participants are randomized to the experimental and control groups. All participants undergo an acupressure program for 15 minutes per day, five days per week, for four weeks. The experimental group are treated with acupressure on correct and efficacious acupoints, while the control group are treated with acupressure on correct and non-efficacious acupoints.

### Intervention Type

Other

### Primary outcome measure

- 1. Adverse drug effects; the research assistant will collect the data from patients' self-report, like the type, frequency and severity of adverse drug effects
- 2. Physiological changes
- 3. Patient's adherence, using their medical charts

All outcomes will be measured at baseline, and every month until they complete their treatment

# Secondary outcome measures

- 1. Health-related quality of life, using the Short-Form-36 Health Survey
- 2. Cure rate, using medical charts

All outcomes will be measured at baseline, and every month until they completed their treatment

# Overall study start date

29/04/2015

# Completion date

28/06/2016

# **Eligibility**

### Key inclusion criteria

Pulmonary tuberculosis patients aged 20 years old or over

### Participant type(s)

**Patient** 

### Age group

Adult

#### Sex

Both

## Target number of participants

130

### Key exclusion criteria

Has cancer, severe liver or renal disease, extra-pulmonary TB, and consciousness unclear

### Date of first enrolment

29/04/2015

### Date of final enrolment

28/03/2016

# Locations

### Countries of recruitment

Taiwan

# Study participating centre Taipei Veterans General Hospital

No.201, Sec. 2 Shipai Road Beitou District Taipei City Taiwan 11217

# Study participating centre Taichung Hospital, Ministry of Health and Welfare

199, sec. 1 Sanmin Road Taichung

# Sponsor information

### Organisation

Taipei Veterans General Hospital

### Sponsor details

No.201, Sec. 2 Shipai Road Beitou District Taipei City Taiwan 11217

### Sponsor type

Hospital/treatment centre

### **ROR**

https://ror.org/03ymy8z76

# Funder(s)

### Funder type

Other

### **Funder Name**

Investigator initiated and funded

# **Results and Publications**

### Publication and dissemination plan

To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not expected to be made available

Study outputs

Output typeDetailsDate createdDate addedPeer reviewed?Patient-facing?Results articleresults01/03/201931/01/2019YesNo