

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

Submission date 29/04/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 02/05/2015	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 31/01/2019	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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
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11221

Additional identifiers

Protocol serial number
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

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Pulmonary tuberculosis

Interventions

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

Intervention Type

Other

Primary outcome(s)

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

Key secondary outcome(s)

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

Completion date

28/06/2016

Eligibility

Key inclusion criteria

Pulmonary tuberculosis patients aged 20 years old or over

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

Taiwan

40343

Sponsor information**Organisation**

Taipei Veterans General Hospital

ROR

<https://ror.org/03ymy8z76>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2019	31/01/2019	Yes	No