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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

Registration date
02/05/2015

Overall study status
Completed

Last Edited
31/01/2019

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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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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

Taiwan
40343

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