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Evaluating the effectiveness of acupuncture for traumatic brain injury and stroke

Submission date
27/07/2021

Recruitment status
No longer recruiting

Registration date
30/07/2021

Overall study status
Completed

Last Edited
30/07/2021

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
A traumatic brain injury (TBI) is an injury that affects how the brain works. A stroke occurs when the blood supply to part of your brain is interrupted or reduced. TBI and stroke are major causes of death and disability worldwide. Acupuncture has been used as a supplemental treatment for patients with TBI and stroke. The aim of this study is to evaluate the effects of acupuncture treatment for patients with TBI and stroke.

Who can participate?
Patients with TBI or stroke

What does the study involve?
Participants are invited for radial pressure wave measurement before and 20 minutes after acupuncture treatment and after 3 weeks of treatment to observe the effect of the acupuncture treatment.

What are the possible benefits and risks of participating?
Patients may benefit from evaluating the progress of treatment in the future. The radial pulse measuring device is non-invasive with no additional risk.

Where is the study run from?
Hualien Tzu Chi Hospital (Taiwan)

When is the study starting and how long is it expected to run for?
January 2020 to December 2020

Who is funding the study?
Hualien Tzu Chi Hospital (Taiwan)

Who is the main contact?
Dr Jhong-Kuei Chen (Public)
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
EJTCM-D-21-00361

Study information

Scientific Title
Using radial pulse wave as hemodynamic measurements to quantify the effects of acupuncture therapy for patients with traumatic brain injury and ischemia stroke

Acronym
RPATTBI

Study objectives
Harmonic indicators may become risk indicators for traumatic brain injury (TBI) patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/01/2020, Institutional Review Board of Hualien Tzu Chi Hospital (707, Sec. 3, Chung-Yang Rd., Hualien, 97002, Taiwan, R.O.C.; +886 (0)3 38561825 Ext. 12124; no email provided), ref: IRB108-200-B

Primary study design
Observational

Study design
Observational case series

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Risk factors in traumatic brain injury patients

Interventions
All subjects undergo radial pressure wave measurement. Spectrum analysis of radial pressure wave is calculated and transformed into Fourier series coefficients Cn and Pn. The clinical research method is divided into two stages, which are the initial measurement and the subsequent follow-up measurement. Each stage will involve two TD01C measurements. The obtained harmonic index will be analyzed by linear regression, chi-square test, etc, to assess whether stroke, traumatic brain injury status and harmonic index are related, and whether these harmonic indicators can assist physicians in monitoring stroke and traumatic brain injury. The process provides a physician's clinical warning function.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Radial pulse spectrum measured using micro-pressure transducer before and 20 minutes after acupuncture treatments
2. Clinical severity measured using Glasgow Coma Scale before and 20 minutes after acupuncture treatments

Key secondary outcome(s)
1. Radial pulse spectrum measured using micro-pressure transducer after 3 weeks of treatment
2. Clinical severity measured using Glasgow Coma Scale after 3 weeks of treatment

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. New stroke (in the last half-year) and traumatic brain injury patients in Hualien Tzu Chi Hospital
2. Any age or gender

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
All

Sex
All

Total final enrolment
20

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
01/05/2020

Date of final enrolment
31/12/2020

Locations

Countries of recruitment
Taiwan

Study participating centre
Hualien Tzu Chi Hospital
No. 707, Sec 3
Zhongyang Road
Hualien
Taiwan
970

Sponsor information

Organisation
Hualien Tzu Chi Hospital

Funder(s)

Funder type
Charity

Funder Name
Buddhist Tzu Chi Medical Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Taiwan

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes