

Evaluating the effectiveness of acupuncture for traumatic brain injury and stroke

Submission date 27/07/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/07/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 30/07/2021	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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)
samtati@gmail.com

Contact information

Type(s)

Public

Contact name

Mr Jhongkuei Chen

Contact details

No. 707, Sec 3
Zhongyang Road
Hualien
Hualien
Taiwan
970
+886 (0)3 8561825
hlmweb@tzuchi.com.tw

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Study design

Observational case series

Primary study design

Observational

Secondary study design

Case series

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

<https://1drv.ms/b/s!AIEOtDPheSzjzmm23FgDMwyB1Nt?e=OkhDHV>

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 C_n and P_n . 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 measure

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

Secondary outcome measures

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

Overall study start date

01/01/2020

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

Age group

All

Sex

Both

Target number of participants

50

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

Sponsor details

No. 707, Sec 3
Zhongyang Road
Hualien
Hualien
Taiwan
970
+886 (0)3 8561825 Ext. 13156
hlmweb@tzuchi.com.tw

Sponsor type

Hospital/treatment centre

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

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

31/08/2021

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