

Transcutaneous pulse oximetry brain monitoring study

Submission date 27/04/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 09/05/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 05/06/2023	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

Acute brain injury is a major public health burden globally and is the leading cause of death and long-term disability among young people. Evidence indicates that early detection of hypoxia (low oxygen in your tissues) and early treatment to prevent brain injury improved patient outcomes. A non-invasive (outside the body) monitoring device has been developed to monitor blood oxygen levels in the brain. The study will compare the new monitoring device with traditional invasive (inside the body) oxygen monitoring.

Who can participate?

Patients with a brain injury requiring invasive brain oxygen monitoring

What does the study involve?

The study involves placing a sensor on either side of the forehead, along with a conventional skin pulse monitor. A small patch of hair may need to be shaved in some patients to allow optimal sensor placement. Sensors will be left in place for approximately 30 minutes. Multiple episodes of monitoring may occur on a given day. Other routinely measured data such as heart rate, respiratory rate and blood pressure will be captured where possible.

What are the possible benefits and risks of participating?

There is no direct benefit from participating in this research. The knowledge gained from this research may be beneficial for other patients, society or science.

Where is the study run from?

NHS Lothian, Edinburgh (UK)

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

February 2022 to June 2024

Who is funding the study?

Cyban Pty Ltd (Australia)

Who is the main contact?

Dr Barry Dixon, barry.dixon@cyban.com.au

Contact information

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Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

313977

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

IRAS 313977, CPMS 52215

Study information

Scientific Title

The T-POT study will be undertaken in patients with a brain injury requiring invasive brain oxygen monitoring. The study will assess the accuracy of a new non-invasive brain pulse oximeter compared with traditional invasive oxygen monitoring

Acronym

T-POT (UK)

Study objectives

The development of an accurate non-invasive method to measure brain oxygen levels could lead to major improvements in patient outcomes through earlier detection and treatment of brain hypoxia, a major cause of secondary brain injury. This simpler, safer, approach would allow monitoring to be part of the routine care of all patients at risk, not just high-risk patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 09/08/2022, Scotland A Research Ethics Committee (Research Ethics Service, 2nd Floor Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG, UK; +44(0)131 465 5680; ruth.fraser4@nhslothian.scot.nhs.uk), ref: 22/SS/0041

Study design

Prospective data collection non-randomized single-center study

Primary study design

Interventional

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Patients with a brain injury requiring invasive brain oxygen

Interventions

One brain pulse oximeter sensor is placed on each hemisphere, along with a conventional skin pulse oximeter. A small path of hair may need to be shaved in some patients to allow optimal sensor placement. The brain pulse oximeter sensors typically only need to be left on for a period of 30 minutes.

Multiple episodes of monitoring may occur on a given day to allow the capture of changes in the partial pressure of oxygen in brain tissue (PbtO₂) levels. The study period will end once the invasive brain oxygen level has been removed and there is no prospect it will recur. Placement of the brain pulse oximeter sensors and data collection will be undertaken by the trained trial researchers. In addition to PbtO₂, other routinely measured ICU physiological data including intracranial pressure, central venous pressure, heart rate, respiration rate and blood pressure will be captured automatically, where possible. Also, information from routine investigational data, such as (CT, MRI, cerebral angiogram, EEG, sensory evoked potentials, doppler US), admission and operative notes will be captured in the case report form to document the timing, size and nature of the brain injury and any complications (for example intracranial bleed, cerebral ischaemia/infarction, hydrocephalus, cerebral oedema or vasospasm) over the study period.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Brain Pulse Oximeter (BPox)

Primary outcome(s)

Brain oxygen levels measured using both the brain pulse oximeter and conventional skin pulse oximeter during the study

Key secondary outcome(s)

Brain oxygen levels where PbtO₂ < 20 mmHg or < 15 mmHg measured using both the brain pulse oximeter and conventional skin pulse oximeter to assess the accuracy to detect an episode during the study

Completion date

30/08/2024

Eligibility

Key inclusion criteria

Patients with invasive brain oxygen monitoring as part of their routine care

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Brain pulse oximeter signal cannot be obtained from at least one brain hemisphere due to an interference issue such as head dressing, severe skin or bone trauma or skull removal preventing brain pulse detection
2. Invasive PbtO2 monitor output believed to be inaccurate by ICU clinicians due to technical limitations with the device

Date of first enrolment

30/04/2023

Date of final enrolment

30/06/2024

Locations**Countries of recruitment**

United Kingdom

Scotland

Study participating centre

NHS Lothian and Reader University of Edinburgh

Waverleygate

2-4 Waterloo Place

Edinburgh

United Kingdom

EH1 3EG

Sponsor information**Organisation**

Cyban Pty Ltd

Funder(s)**Funder type**

Industry

Funder Name
Cyban Pty Ltd

Results and Publications

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No