ISRCTN28562529 https://doi.org/10.1186/ISRCTN28562529

Transcutaneous pulse oximetry brain monitoring study

Submission date
27/04/2023

Recruitment status
No longer recruiting

Registration date
09/05/2023

Overall study status
Completed

Last Edited
05/06/2023

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
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

Type(s)
Principal investigator

Contact name
Dr Jonathan Rhodes

Contact details
ICU, Ward 118, Royal Infirmary of Edinburgh
Little France Crescent
Edinburgh
United Kingdom
EH16 4SB
+44 (0)131 242 1186
jrhodes1@exseed.ed.ac.uk

Type(s)
Scientific

Contact name
Dr Barry Dixon

Contact details
L18
1 Nicholson Street
East Melbourne VIC
Australia
3002
+613439618815
barry.dixon@cyban.com.au

Type(s)
Public

Contact name
Mr David Mitchell

Contact details
L18
1 Nicholson Street
East Melbourne VIC
Australia
3002
+61458750078
david.mitchell@cyban.com.au

Additional identifiers

Integrated Research Application System (IRAS)
313977

Central Portfolio Management System (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

Primary study design
Interventional

Study design
Prospective data collection non-randomized single-center study

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