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New quality criteria of eye nerve sheath diameter measurements in the diagnosis of increased pressure inside the skull in severe brain trauma

Submission date
07/03/2017

Recruitment status
No longer recruiting

Registration date
04/04/2017

Overall study status
Completed

Last Edited
18/02/2022

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Traumatic brain injury (TBI) is an injury to the brain caused by a head injury (trauma to the head). Depending on the part of the brain that is injured, it can cause changes in behaviour, physical abilities or even personality. There is a high risk of developing complications of severe brain injury such as a buildup of pressure inside the skull (increased intracranial pressure). This can starve parts of the brain of oxygen (cerebral ischaemia), leading to brain damage or even death. To prevent this, increases in intracranial pressure must be detected early. This is usually done by inserting a special tube (catheter) into the brain via a hole that is drilled in the skull or using a CT scan. Recently, ultrasound examination of the eye nerve has been found to be a useful and easy bedside tool to detect the increased intracranial pressure by measuring the diameter of the sheath around eye nerve. The aim of this study is to find out whether this technique is as accurate at measuring the pressure inside the skull as standard techniques.

Who can participate?
Adult patients on the neurocritical care unit with a severe TBI.

What does the study involve?
All participants undergo testing and monitoring for increased intracranial pressure using standard techniques. This involves having a brain scan using CT scanning and having a catheter inserted into their brains through a small hole drilled in the skull. Participants also have the diameter of the sheath surrounding the optic (eye) nerve measured using ultrasound scanning, which is used to calculate the pressure in the skull. The results are then compared in order to see how accurate the ultrasound technique is.

What are the possible benefits and risks of participating?
Participants benefit from receiving additional close monitoring while they are in hospital. There are no risks involved with participating.

Where is the study run from?
King Saud Medical City Hospital (Saudi Arabia)

When is the study starting and how long is it expected to run for?
November 2016 to August 2018

Who is funding the study?
King Saud Medical City Hospital (Saudi Arabia)

Who is the main contact?
Dr Ibrahim Soliman

Contact information

Type(s)
Scientific

Contact name
Dr Ibrahim Soliman

Contact details
Neuro Critical Care Unit (NCCU)
King Saud Medical City (KSMC)
Al Imam Turki ibn Abdullah Ibn Muhammad, Ulaishah
Riyadh
Saudi Arabia
12746

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
New quality criteria of optic nerve sheath diameter measurements in the diagnosis of increased intracranial pressure in severe traumatic brain injury

Study objectives
The aim of this study is to apply a new quality criteria for obtaining sonographic ONSD measurements (for diagnosis of elevated intracranial pressure) to standardise it by improving image quality and to compare such ONSD measurements to invasive intraparenchymal ICP measurements in patients with severe traumatic brain injury.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Prospective observational cohort study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Severe traumatic brain injury

Interventions
One hundred patients with acute severe TBI (GCS<8) will be registered in the study based on the performed power sample analysis. All patients will be evaluated clinically and by computed tomography upon inclusion. An intra-parenchymal ICP catheter will be inserted by neurosurgeons per severe TBI monitoring protocol either in the operating room or in the NCCU. Intracranial pressure will be measured using a camino intra-parenchymal catheter (Camino Laboratories, San Diego, CA, USA) will be inserted by neurosurgeons in the frontal region of each patient. ICP measurements will be continuously monitored and will be recorded within 1-2 minutes of ONSD measurement. Elevated ICP is defined as 20 mmHg or greater.

At baseline, all patients undergo a CT scan. 10-15 minutes later, the optic nerve sheath diameter will be measured for both eyes using ultrasound by a single expert sonographer who is blinded to patient identity and to invasive ICP findings. Sonographic examinations will be conducted using a Philips HD11XE (Philips Medical Systems; Bothell, WA, USA) equipped with a 10-20MHz linear transducer. All patients will be examined in the supine position. The ONSD will be measured according to the new quality criteria. In each patient, the eye with the larger ONSD will be compared to ICP (recorded within 1-2 minutes after ONSD measurement). ICP and ONSD measurements will be measured 5 times (0, 6, 12, 24 and 48 hours) per patient over 48 hours, for a total of 500 measurements.

Intervention Type
Other

Primary outcome(s)
Correlation between the ONSD and ICP the ONSD measurement using the new sonographic quality criteria and the invasive ICP measured by parenchymal ICP monitor within the first 48 hours of Severe TBI

Key secondary outcome(s))
1. Ideal ONSD threshold value corresponding to elevated ICP is measured by the receiver operating characteristic (ROC) curves at the end of the study
2. Unfavorable outcome, that is, death, and vegetative or severe disability on the Glasgow outcome scale (GOS) at discharge from Neurocritical Care Unit (NCCU)
3. Incidence of brain death during NCCU stay is measured by dividing the number of brain death cases by the total number of study cases at the end of the study
4. NCCU average length of stay for severe TBI cases is measured by dividing the total length of stay by total number of discharges at the end of the study

Completion date
31/08/2018

Eligibility

Key inclusion criteria
1. Patient on the neurocritical care unit
2. Aged 18 years and over
3. Acute Severe TBI (Marshall Scale ≥ II and GCS ≤ 8) within the first 48 hours after trauma who has Parenchymal ICP inserted

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Orbital trauma
2. Known disease of the optic nerve

Date of first enrolment
01/04/2017

Date of final enrolment
30/06/2018

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
King Saud Medical City Hospital
Neurocritical care unit (NCCU)
Al Imam Turki ibn Abdullah Ibn Muhammad, Ulaishah
Riyadh
Saudi Arabia
12746

Sponsor information

Organisation
King Saud Medical City

ROR
https://ror.org/03aj9rj02

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
King Saud Medical City Hospital

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?
Results article		30/04/2018	18/02/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes