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Ultrasound-guided fluid management versus standard care in critically ill patients with severe traumatic brain injury

Submission date
20/11/2026

Recruitment status
No longer recruiting

Registration date
21/11/2026

Overall study status
Completed

Last Edited
20/11/2026

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
Patients with severe traumatic brain injury (TBI) require careful intravenous (IV) fluid management while on a breathing machine in the intensive care unit (ICU). Giving too little fluid can reduce blood flow to the injured brain and cause further brain damage, while giving too much fluid can worsen brain swelling (cerebral oedema) and cause fluid build-up in the lungs (acute pulmonary oedema). Conventionally, doctors guide fluid therapy using blood pressure, heart rate, and urine output. This study aims to find out whether adding painless bedside ultrasound scans of the body's main vein (the inferior vena cava) helps doctors give a more accurate amount of balanced IV fluid and reduce lung and brain swelling compared with standard monitoring alone.

Who can participate?
Adult patients aged 18 to 65 years admitted to the Trauma or Neuro ICU at Hospital Universiti Sains Malaysia with severe traumatic brain injury (Glasgow Coma Scale score 3–8) who require a breathing machine (mechanical ventilation) for at least 24 hours.

What does the study involve?
Because eligible patients are unconscious and on a breathing machine, written informed consent is obtained from their next of kin before participation. Participants are randomly allocated into two equal groups for their first 72 hours in the ICU. One group receives standard fluid management guided every 6 hours by blood pressure, heart rate, and urine output. The other group receives standard care plus bedside ultrasound measurements of the inferior vena cava every 6 hours to guide 250 mL IV fluid boluses of a balanced crystalloid solution (Sterofundin®). Daily fluid balance, chest X-rays, lung ultrasounds, repeat brain CT scans, length of ICU stay, and functional recovery at ICU discharge and 30 days after hospital admission are recorded.

What are the possible benefits and risks of participating?
Ultrasound-guided fluid assessment may help prevent both under-hydration and fluid overload,

potentially reducing lung and brain swelling complications during ICU stay. There are no added risks from participating, as bedside ultrasound is non-invasive and painless, and all participants receive standard ICU monitoring and balanced IV fluid care.

Where is the study run from?
Hospital Universiti Sains Malaysia (HUSM), Kubang Kerian, Kelantan, Malaysia.

When is the study starting and how long is it expected to run for?
October 2022 to July 2023.

Who is funding the study?
Investigator-initiated and funded by Universiti Sains Malaysia (USM).

Who is the main contact?
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Additional identifiers

Study information

Scientific Title
Optimizing the adequacy of fluid during balanced isotonic fluid management in the ventilated severe traumatic brain injury (TBI) patients using an ultrasound-guided technique

Study objectives
General Objective
To compare the effectiveness of additional ultrasound-guided fluid assessment (by measuring the inferior vena cava diameter [IVCd] and distensibility index [DI]) with the conventional fluid therapy strategy alone during balanced isotonic fluid management in ventilated severe traumatic brain injury (TBI) patients.

Specific Objectives
1. To compare the mean cumulative fluid balance every 24 hours for 72 hours between the inferior vena cava (IVC) diameter-guided group and the conventional group.
2. To compare the frequency and proportion of new or worsening acute pulmonary oedema (from chest X-ray and lung ultrasound) every 24 hours for 72 hours between the two groups.
3. To compare the frequency and proportion of new or worsening cerebral oedema (from repeat brain CT scan) between the two groups.
4. To compare the mean length of ICU stay between the two groups.
5. To compare the Glasgow Outcome Scale (GOS) score at discharge from the ICU and at Day 30 of hospital admission between the two groups.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/08/2022, Human Research Ethics Committee Universiti Sains Malaysia (USM HREC) (Universiti Sains Malaysia, Health Campus, Kubang Kerian, 16150, Malaysia; +609 - 767 3000/2354 /2362; jepem@usm.my), ref: USM/JEPeM/22040191

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Health services research, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Severe traumatic brain injury (Glasgow Coma Scale score 3–8) requiring mechanical ventilation and ICU admission for cerebral protection (for at least 24 hours) regardless of conservative or surgical management

Interventions
Randomisation and Allocation: Eligible patients with severe traumatic brain injury (TBI) admitted to the Trauma or Neuro Intensive Care Unit (ICU) are randomised in a 1:1 ratio using computer-generated block randomisation (block size of 5 via randomization.com) with allocation concealed in sealed opaque envelopes opened upon ICU admission. Both groups receive standard ICU neuroprotective care, mechanical ventilation, sedation (propofol and fentanyl infusions), and weight-based maintenance fluid using balanced isotonic crystalloid (Sterofundin®) calculated via the Holliday-Segar formula over a 72-hour cerebral protection period.

Intervention Group (Ultrasound-Guided Fluid Management; Group IVCd, n = 35): In addition to standard monitoring, fluid therapy is guided by bedside subxiphoid M-mode ultrasonography (Samsung HS30®, 3 MHz convex probe) performed at baseline (ICU admission) and every 6 hours for 72 hours. If the inferior vena cava diameter (IVCd) is < 21 mm and the distensibility index (DI) is > 18%, a 250 mL intravenous bolus of Sterofundin® is infused over 30 minutes followed by repeat ultrasound reassessment (repeated up to 3 times if targets are not achieved).

Control Group (Conventional Fluid Management; Group Control, n = 35): Fluid therapy is guided every 6 hours for 72 hours using conventional clinical haemodynamic parameters (blood pressure, heart rate, and urine output). If hypotension and tachycardia suggestive of hypovolaemia occur, a 250 mL intravenous bolus of Sterofundin® is infused over 30 minutes followed by clinical reassessment (repeated up to 3 times if haemodynamic targets are not achieved).

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Cumulative fluid balance measured using total fluid input (including intravenous fluids, blood products, medications, and nutrition) minus total fluid output (urine output, drain losses, and insensible/other recorded outputs) in millilitres (mL) recorded from ICU fluid balance charts at 24, 48 and 72 hours after initiation of cerebral protection in the ICU

Key secondary outcome(s)
1. Incidence of new or worsening acute pulmonary oedema (APO) measured using the presence of acute pulmonary oedema features on chest X-ray (assessed by a blinded radiologist) and signs

of wet lungs (B-lines) on bedside lung ultrasound (performed by a blinded assessor) at 24, 48 and 72 hours after initiation of cerebral protection

2. Incidence of new or worsening cerebral oedema measured using the presence of new or worsening cerebral oedema features on repeat non-contrast brain computed tomography (CT) scan reviewed by a blinded radiologist at any time within the 72-hour cerebral protection period (compared against baseline admission brain CT)

3. Length of Intensive Care Unit (ICU) stay measured using the duration of ICU admission in days calculated from ICU admission date and time to ICU discharge date and time from hospital medical records at ICU discharge

4. Functional neurological outcome measured using the Glasgow Outcome Scale (GOS; dichotomised into favourable outcome [scores 1–2: good recovery or moderate disability] and unfavourable outcome [scores 3–5: severe disability, persistent vegetative state, or death]) assessed via clinical review or follow-up telephone interview at ICU discharge and at Day 30 of hospital admission

Completion date
30/07/2023

Eligibility

Key inclusion criteria
1. Adults aged 18–65 years
2. Severe traumatic brain injury (Glasgow Coma Scale score 3–8)
3. Requiring mechanical ventilation and ICU admission for cerebral protection (for at least 24 hours), regardless of conservative or surgical management

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
70

Key exclusion criteria
1. Poor baseline cardiac contractility (left ventricular ejection fraction < 50%) due to cardiomyopathy or underlying heart disease

2. Underlying chronic kidney disease or dialysis-dependent end-stage renal failure
3. Polytrauma involving major extracranial vital organs (severe lung injury requiring high ventilator settings, intra-abdominal injury, or major vascular injury)
4. Coagulopathy
5. Pregnancy
6. Obesity or severe abdominal distension resulting in an inadequate ultrasound acoustic window
7. High positive end-expiratory pressure (PEEP) > 14 mmHg

Date of first enrolment
01/10/2022

Date of final enrolment
30/06/2023

Locations

Countries of recruitment
Malaysia

Sponsor information

Organisation
Universiti Sains Malaysia

ROR
https://ror.org/02rgb2k63

Funder(s)

Funder type

Funder Name
Universiti Sains Malaysia

Alternative Name(s)
University of Science, Malaysia, Universiti Sains Malaysia (USM), Universiti Sains Malaysia | George Town, Malaysia | USM, usmofficial1969, University Sains Malaysia (USM), University Sains Malaysia, Science University of Malaysia, USM

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Malaysia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available