

Fluid administration strategy in severe traumatic brain injury

Submission date 23/10/2019	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/10/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 28/10/2019	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

Traumatic Brain Injury (TBI) is an injury to the brain caused by a trauma to the head (head injury). There are many possible causes, including road traffic accidents, assaults, falls and accidents at home or at work. Since TBI is a major health problem all efforts are being made to improve the outcomes of TBI victims. None of the TBI management guidelines addresses the fluid balance

Who can participate?

Patients aged 14 or above with severe TBI

What does the study involve?

Our study will have two groups with random assignment. In one group we will treat the patients following our ICU protocol which is adopted from Brain Trauma Foundation guidelines.

The second group will also follow the same protocol of management, and will be treated exactly the same way, but we will aim for maintaining a 24 hours balance of +/- 500 ml, while not interfering with the management hemodynamic targets, this will be done in the first 7 days after the trauma.

Upon ICU discharge we will evaluate the patients outcome using a score that ranges from 1 - 5 for the functionality of the patient (5 is best, 1 is worst).

Our hypothesis is that maintaining a balance of fluids will result in better outcomes.

What are the possible benefits and risks of participating?

Possible benefits include achievement of favourable Glasgow Outcome Score (4 or 5) upon ICU discharge, fewer ventilator days and thus fewer complications related to mechanical ventilation and less ICU and hospital stay. We are expecting no risks more than would be expected for a critically ill patient treated in ICU

Where is the study run from?

King Saud Medical City, Saudi Arabia

When is the study starting and how long is it expected to run for?
November 2019 to December 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
H1IR - 17 - DEC 18 - 01

Study information

Scientific Title
Restricted versus liberal fluid administration strategy in severe traumatic brain injury (RELIST). A randomized clinical trial

Acronym

RELIST

Study objectives

Maintaining a zero balance of fluids for TBI patients will result in better outcomes as compared to a positive balance

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 20/06/2019, IRB of King Saud Medical City (Saudi Arabia, Riyadh, 11373; irb@ksmc.med.sa; +966 0114355555- ext 2345) ref: H1IR-17-DEC 18-01

Study design

Open-label randomized controlled trial of two arms compared head to head

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Isolated, non penetrating severe traumatic brain injury (GCS < 9)

Interventions

The study will recruit patients aged 14 or above (14 is the age of adulthood in Saudi Arabia) who are victims of severe TBI (GCS < 9) within 24 hours of the incidence of trauma. The main intervention of the study is controlling the fluid balance in the first 7 days to keep it ± 500 ml /day as compared to no interference with balance in the control group. Otherwise, both groups are treated similarly, according to our unit protocol adopted from guidelines of Brain Trauma Foundation.

Intervention: Maintaining a 24 hours balance of ± 500 ml , for the first 7 days. While following the TBI protocol as per the guidelines. Daily balance may be controlled using diuretics, and if needed vasopressors to maintain hemodynamic targets.

Control: This group also follows the TBI protocol as per the guidelines, except there is no interference with the fluid balance

Intervention Type

Mixed

Primary outcome measure

Percentage of patients with favorable Glasgow Outcome Scale (4 or 5) upon ICU discharge

Secondary outcome measures

1. Percentage of patients with favorable GOS at 6 months
2. ICU length of stay and mortality
3. Development of pulmonary oedema
4. Days on TBI management protocol
5. Days on mechanical ventilation

Overall study start date

01/01/2019

Completion date

31/12/2020

Eligibility

Key inclusion criteria

1. Age ≥ 14 years
2. Severe TBI (GCS <9)
3. Within 24 hours of the incidence of trauma provided that the resuscitation phase is complete (post-resuscitation phase)
4. Isolated non-penetrating head injury
5. Clinical necessity for ICP management per BTF recommendations
6. Mechanically ventilated, without any evidence of respiratory dysfunction (P/F ratio ≥ 250).
7. Hemodynamically stable or on vasopressor support for standardized CPP management according to BTF recommendations: MAP ≥ 65 mmHg
8. SBP ≥ 90 mmHg

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

600

Key exclusion criteria

1. Pregnancy
2. Neurological examination suggesting eminent brain death
3. Multiple trauma
4. Severe chronic heart failure (NYHA 4)
5. Bleeding disorders and/or ICP monitoring contraindicated for other reasons.

- 6. Impaired renal function (Creatinine > 200 mmol/L)
- 7. Patients without fixed address (impossible to follow-up)

Date of first enrolment

01/11/2019

Date of final enrolment

31/10/2020

Locations

Countries of recruitment

Saudi Arabia

Study participating centre

King Saud Medical City

Al-shemaisi

Riyadh

Saudi Arabia

11373 - Shemaisi

Sponsor information

Organisation

King Saud Medical City

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<https://www.ksmc.med.sa>

ROR

<https://ror.org/03aj9rj02>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

We intend to publish the results of the trial in peer reviewed journals.

Intention to publish date

01/01/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to lack of consent from participants to share their data.

IPD sharing plan summary

Not expected to be made available