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Fluid administration strategy in severe traumatic brain injury

Submission date
23/10/2019

Recruitment status
No longer recruiting

Registration date
29/10/2019

Overall study status
Completed

Last Edited
28/10/2019

Condition category
Injury, Occupational Diseases, Poisoning

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