

# Fluid administration strategy in severe traumatic brain injury

<b>Submission date</b> 23/10/2019	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 29/10/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 28/10/2019	<b>Condition category</b> 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?  
Dr Waleed Aletreby  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
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**

Intentional

## **Study type(s)**

Treatment

## **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  $\pm$  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  $\pm$  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(s)**

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

## **Key secondary outcome(s)**

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

**Completion date**

31/12/2020

## Eligibility

**Key inclusion criteria**

1. Age  $\geq$  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  $\geq$  250).
7. Hemodynamically stable or on vasopressor support for standardized CPP management according to BTF recommendations: MAP  $\geq$  65 mmHg
8. SBP  $\geq$  90 mmHg

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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

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

## **Funder(s)**

**Funder type**  
Other

**Funder Name**  
Investigator initiated and funded

## **Results and Publications**

### **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