TRansfusion strategies in Acute brain Injured patients: TRAIN Study; A Prospective Multicenter Randomized Interventional Study

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Ethical review	Approved WMO
Status	Pending
Health condition type	Structural brain disorders
Study type	Interventional

Summary

ID

NL-OMON50333

Source
ToetsingOnline

Brief title
TRAIN study

Condition

- Structural brain disorders
- Aneurysms and artery dissections

Synonym
brain hemorrhage, brain injury caused by accident

Research involving
Human

Sponsors and support

Primary sponsor: Hopital Erasme Bruxelles
Source(s) of monetary or material Support: European Society of Intensive Care Medicine (ESICM)

Intervention

Keyword: anemia, blood transfusion, brain injury, clinical study, outcome

Outcome measures

Primary outcome

The primary outcome is neurological outcome, evaluated using extended Glasgow Outcome Scale (eGOS), at 180 days after the initial injury.

Secondary outcome

Secondary outcomes include, amongst all, 28-day survival, intensive care unit (ICU) and hospital length of stay, the occurrence of extra-cerebral organ dysfunction/failure and the development of any infection or thromboembolic events (either venous or arterial).

Study description

Background summary

Although blood transfusions can be lifesaving in severe hemorrhage, they could also result in several potential complications. As anemia has also been associated with poor outcome in critically ill patients, optimal transfusion trigger is a real challenge for clinicians. This is even more important in patients with acute brain injury who were not specifically evaluated in previous large randomized clinical trials dealing with the optimal transfusion threshold. Neurological patients may be particularly sensitive to anemic brain hypoxia because of the exhausted cerebrovascular reserve, which adjust cerebral blood flow to tissue oxygen demand.

Study objective

The aim of the current study is to determine whether a *liberal* strategy of maintaining Hb concentrations above 9 g/dL would result in a different neurological outcome when compared to a *restrictive* approach to red-cell transfusion to avoid hemoglobin concentrations < 7 g/dL in critically ill anemic patients (i.e. Hb <= 9 g/dL) with acute brain injury.

Study design

Prospective, multi-center, randomized, pragmatic, controlled international study conducted at intensive care units (ICUs).

Intervention

A *liberal* strategy of maintaining Hb concentrations above 9 g/dL will be compared to a *restrictive* approach to red-cell transfusion to avoid hemoglobin concentrations < 7 g/dL in critically ill anemic patients (i.e. Hb <= 9 g/dL) with acute brain injury.

Study burden and risks

There is a very small risk of transfusion reactions or infections when blood transfusions are administered. However, surveillance on both complications will be strictly applied and standard surveillance for infections are in place as part of standard practice, minimising infection risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Age >=18 years and <= 80 years
2. Acute Brain Injury: Traumatic Brain Injury; Subarachnoid Hemorrhage; Intracranial Hemorrhage (ICH: either primary or anticoagulants-associated)
3. Glasgow Coma Score (GCS) on randomization <= 13
4. Expected ICU stay > 72 hours
5. Hemoglobin (Hb) concentration <= 9 g/dL

Exclusion criteria

1. Post-anoxic coma; status epilepticus without underlying brain injury; central nervous system (CNS) infections (community-acquired; hospital-acquired; ventriculitis; post-operative)
2. Known previous neurological disease, causing significant cognitive and/or motor handicap
3. ICH due to artero-venous malformation (AVM) or brain tumor
4. Inability (religious reasons) or reduced ability (lack of compatible blood) to receive blood products
5. Active and uncontrolled bleeding at the time of enrollment
6. GCS of 3 with both fixed and dilated pupils; Brain death or imminent death (within 24 hours)
7. Pregnancy
8. Medical need to keep Hb levels > 8-9 g/dL (e.g. active coronary disease or severe cardiac disease)
9. DNE (do not escalate) orders
10. Previous allo-immunisation due to transfusion limiting RBC availability

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2020
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO Date:	21-04-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT02968654
CCMO	NL61748.078.18