Impact of Fever Prevention in Brain Injured Patients (INTREPID)

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The objective of this study is to assess if 1) by using the Arctic Sun® 5000 Temperature Management System occurrence of fever can be prevented and 2) patients treated with the Arctic Sun® 5000 Temperature Management System have a better recovery...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Vascular haemorrhagic disorders
Study type	Interventional

Summary

ID

NL-OMON46804

Source
ToetsingOnline

Brief title
INTREPID Study

Condition

- Vascular haemorrhagic disorders

Synonym
brain injury, stroke

Research involving
Human

Sponsors and support

Primary sponsor: C.R. Bard
Source(s) of monetary or material Support: Bard Medical Division

Intervention

Keyword: fever, neurological outcome, randomized trial, stroke

Outcome measures

Primary outcome

The primary outcome endpoint is the daily average fever burden (°C-hour) between randomization and Day 14 (336 hours) or ICU exit, whichever comes first.

The key secondary outcome endpoint (to which the study was powered) is the level of functional independence at 90 days post-injury (3-month) follow-up based on the modified Rankin Scale.

Secondary outcome

* Neurologic outcome measures

- Modified Rankin Scale measured at 6- and 12-months

- National Institutes of Health Stroke Scale measured at 3- and 6-months

- Barthel Index measured at 3- and 6-months

- Glasgow Outcome Scale Extended measured at 3- and 6-months

- Montreal Cognitive Assessment measured at 3- and 6-months

* Intensive Care Unit length of stay

* ICU Delirium

* Use of mechanical ventilation

* Hospital length of stay

* Mortality [7-day (or hospital discharge), 3-, 6-, and 12-month]

Study description

Background summary

Multiple studies demonstrate that fever or elevated body temperature is associated with poor outcomes in brain injured patients; however, there are no conclusive studies that demonstrate that fever prevention/controlled normothermia is associated with better outcomes. This study will be conducted to assess the impact of advanced temperature control to prevent fever in brain injured patients.

Study objective

The objective of this study is to assess if 1) by using the Arctic Sun® 5000 Temperature Management System occurrence of fever can be prevented and 2) patients treated with the Arctic Sun® 5000 Temperature Management System have a better recovery and neurological outcome compared to patients where this device has not been used and fever has not been prevented.

Study design

This is a randomized, controlled multicenter clinical investigation designed to assess fever burden and early, short- and long-term clinical outcomes of fever prevention using the Arctic Sun 5000 Temperature Management System (test device) compared to standard fever care in the treatment of moderate-to-severe brain injured patients.

Treatment Arms:
Fever Prevention Group * Subjects randomized to the "fever prevention group" will be treated with the Arctic Sun® 5000 Temperature Management System in order to maintain normothermia (target temperature 37°C). Normothermia will be maintained through day 14 of the study or until the subject is discharged from the ICU, whichever comes first.
Control Group * In subjects randomized to the "control group", fever may or may not develop. Should fever develop, it will be managed according to a standard, escalating treatment algorithm. Subjects will be treated according to the protocol through day 14 of the study or until the subject is discharged from the ICU, whichever comes first.

Intervention

See study design

Study burden and risks

Patients will be followed up at the following time points:
- 5 days after the acute phase or at hospital discharge, whichever comes first
- 3 months after their brain injury
- 6 months after their brain injury
- 12 months after their brain injury (this visit may be over the phone)
During the follow up visits several standard neurologic assessments will be performed.

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Adult patients >=18 and <=85 years of age (for patients >80 and <=85 years of age, the qualifying mRS must be <= 0)
* Admitted with a primary neurological diagnosis of ischemic stroke (AIS), intracerebral

hemorrhage (ICH), or subarachnoid hemorrhage (SAH)
* Prior to onset of acute symptoms, was considered functionally independent (mRS 0-2)
* Disease-specific criteria:
For AIS patients:
- imaging confirmed diagnosis
- NIHSS ><= 6 at the time of consideration of enrollment
For ICH patients:
- imaging confirmed diagnosis
- NIHSS ><= 6 at the time of consideration of enrollment
- GCS ><= 5 at the time of consideration of enrollment
- ICH volume of 1-60 cc
For SAH patients:
- aneurysmal SAH confirmed within 24 hrs of symptom onset
- admission imaging shows Fisher Grade 2, 3 or 4
- WFNS Grade II-IV
- neurological stability within 6-48 hrs of endovascular or surgical procedure (if performed)

Exclusion criteria

* Fever (>= 38°C) for more than one hour prior to study enrollment
* Pre-existing neurological, psychiatric, or other condition that would confound neurological assessment or would make it difficult to accurately assess neurologic and/or functional outcome
* Has a pre-morbid condition that in the opinion of the investigator suggests poor likelihood of survival to 6 months
* Is undergoing therapeutic hypothermia therapy
* Has sustained neurological injury felt to be catastrophic with little chance of recovery or is on comfort measures only
* Has a skin condition in which the use of the ArcticGel Pads is contraindicated
* Participation in a concurrent interventional study
* In the investigator*s opinion is likely to stay in the ICU <= 72 hours
* Is known to be pregnant
* fever (>= 38°C) at time of study enrollment

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	40
Type:	Anticipated

Medical products/devices used

Generic name:	Arctic Sun 5000 Temperature Management System
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	03-11-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	06-04-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NCT02996266
CCMO	NL62306.098.17