ISRCTN45963643 https://doi.org/10.1186/ISRCTN45963643

Exploratory study to assess the practicality of a method for potentially evaluating the safety and clinical advantages of the MONTE monitor, for the management of intracranial hypertension in patients with traumatic brain injury in the future

Submission date
05/12/2023

Recruitment status
Recruiting

Registration date
16/02/2024

Overall study status
Ongoing

Last Edited
25/11/2026

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Severe traumatic brain injury (sTBI) is an injury of the brain caused by an external force to the head, mainly due to road traffic accidents, falls and assaults. sTBI can lead to increased brain pressure, which may cause additional brain damage. For this reason it is important to monitor the pressure of the brain for patients with sTBI in the intensive care unit (ICU) with bedside monitors.
The standard of care for elevated brain pressure in patients with sTBI follows a step-wise approach, the higher the step the more the treatment intensity increases. The current guidelines suggest starting treatments with a higher treatment intensity when the pressure rises above a fixed threshold. This treatment strategy is the current gold standard of care for TBI. However, a more personalized strategy for brain pressure management is necessary.
The MONTE (Monitor for iNTracranial hypErtension) is a monitoring tool for the management of patients with sTBI who require invasive ICP monitoring. The MONTE processes routinely collected monitoring data with advanced mathematic algorithms, and based on these calculations the software provides new information to the clinician. The ultimate goal of the MONTE software is to provide monitoring information that will help the clinician in choosing the best treatment for elevated brain pressure in patients with sTBI.
The aim of this study is to test whether the protocol of the procedure to assess the safety and effectiveness of the MONTE software is achievable. If the study is successful, that is, if it is found that the procedure is suitable to assess the safety and effectiveness of the MONTE, the same procedure used in this study will be applied to a larger study (more patients will be enrolled).

Who can participate?
Patients over the age of 18 years who have suffered brain trauma and need brain pressure monitoring

What does the study involve?
Participants will be randomly assigned to a control group (standard monitoring) or an intervention group (standard monitoring and MONTE software). Patients in both groups will be treated according to current guidelines for treating patients with sTBI. In patients in the control group, brain pressure will be monitored by using standard monitoring devices. In patients in the intervention group, in addition to the standard monitoring devices, the MONTE is available to the treating clinician, to provide them with additional information about the brain pressure of the patient, including predictions of future elevated pressures and a quantification of previous pressure values, as well as the reaction of the blood vessels of the brain to changes in blood pressure. Participants in both groups will be evaluated every 4 hours, after which the treating physician has to complete a short questionnaire about the patient's course of treatment. Participants will participate in the clinical study as long as it is necessary to monitor brain pressure, for no more than 1 week. Six months after admission to the intensive care unit, the patient will be contacted by telephone to answer some questions about their recovery. The patient is not required to undergo any hospital visits in addition to the standard treatment.

What are the possible benefits and risks of participating?
The MONTE may or may not be beneficial in treating sTBI or reducing the symptoms of patients. The information learned from this study might help to better understand the use of the MONTE software or might help in the development of a new medical device for the treatment of severe brain injury in future patients.
Participation in this study entails no additional costs, but it also offers no financial benefits.
No additional risks related to the participation in this study are expected for patients. The study does not specify diagnostic or therapeutic interventions to be taken in response to the information provided by the MONTE software. The management of the participant is expected to follow the standard of care and the current recommendations for sTBI.

Where is the study from?
University Hospital Leuven (Belgium)

When is the study starting and how long is it expected to run for?
June 2022 to January 2026

Who is funding the study?
KU Leuven (Belgium)

Who is the main contact?
Prof. Dr. Geert Meyfroidt, geert.meyfroidt@uzleuven.be

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Additional identifiers

Eudamed nr
CIV-23-03-042694

Study information

Scientific Title
Pilot study on the feasibility of the methodology for a future prospective evaluation of safety and clinical benefits of the MONTE monitor, for the management of intracranial hypertension in patients with traumatic brain injury

Acronym
MONTE study 1

Study objectives
The main hypothesis of the study is that the methodology which was designed to assess the safety and effectiveness of the MONTE monitor is feasible and can be used in future, larger and properly powered clinical investigations. Moreover, the results and experience that will derive from this exploratory pilot study will provide useful information and insights for the future development of the MONTE monitor.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 29/06/2023, CT college (Galileelaan 5, box2, Brussels, 1210, Belgium; +32 (0)2 5249797; ct.college@health.fgov.be), ref: CIV-23-03-042694

Primary study design
Interventional

Study design
Pilot pre-market investigator-driven academic international (European) multicenter randomized exploratory first-in-human clinical investigation with a medical device

Study type(s)
Other

Health condition(s) or problem(s) studied
Severe traumatic brain injury requiring sedation to control intracranial pressure

Interventions
The investigational medical device of this study, which is called MONTE, provides novel monitoring information to the clinicians in charge of the management of patients with severe Traumatic Brain Injury (TBI). The investigational device is not CE-marked.

The investigational medical device (the MONTE software) will be blinded for the control group and non-blinded for the intervention group. A block randomization scheme with blocks of four patients will be used for the study. Only stratification per center will be used. To receive a group assignment, site research personnel will enter stratification information into an electronic randomization application hosted by the investigators in UZ Leuven. The code for randomization blinding is stored in the randomization tool (developed in REDCap) with restricted access.

Participants will be randomly assigned to a control group (standard monitoring) or an intervention group (standard monitoring and MONTE software). Patients in both groups will be treated according to current guidelines for treating patients with sTBI. In patients in the control group, brain pressure will be monitored by using standard monitoring devices. In patients in the intervention group, in addition to the standard monitoring devices, the MONTE is available to the treating clinician, to provide them with additional information about the brain pressure of the patient, including predictions of future elevated pressures and quantification of previous pressure values, as well as the reaction of the blood vessels of the brain to changes in blood pressure. Patients in both groups will be evaluated every 4 hours, after which the treating physician has to complete a short questionnaire about the patient's course of treatment.

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Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
MONTE

Primary outcome(s)
1. The feasibility of the proposed methodology, quantified with the following measures:
1.1. The adherence to the number of clinical evaluations is equal to or higher than 75%
1.2. The adherence to the number of clinical evaluations is equal to or higher than 75%
Clinical evaluations will last up until 1 week after the patient's study inclusion OR will be interrupted earlier in case invasive ICP monitoring is interrupted for more than 24 hours OR in case the patient undergoes decompressive craniectomy

Key secondary outcome(s)
1. The number of performed clinical evaluations without technical problems is equal to or higher than 90%. Clinical evaluations will last up until 1 week after the patient's study inclusion OR will be interrupted earlier in case invasive ICP monitoring is interrupted for more than 24 hours OR in case the patient undergoes decompressive craniectomy.
2. Estimated costs and time required for an interventional study that is powered for safety and clinical benefits (effectiveness). Based on the pilot study, a future larger-scale clinical investigation can be planned, which will be properly powered for effectiveness and safety endpoints. Proper power calculation will give us an estimation of costs for the future study (based on the amount of patients). The time needed for the future study, based on the power calculation, is defined as the start of study patient recruitment until 6 months follow-up of the last patient (last patient last visit).
3. Validity of the randomization procedure, evaluated by verifying that at the end of the study period the same number of patients were recruited in both randomization groups.
4. Estimated recruitment rates, drop-out rate and incidence of ICU mortality
5. Insights on the true effect of the intervention:
5.1. Percentage of time with harmful ICP doses
5.2. Number of events of harmful ICP doses
5.3. Number of events of extremely elevated ICP (defined as ICP >28 mmHg for more than 10 minutes)
5.4. Percentage of time with impaired cerebrovascular autoregulation (defined as low-frequency autoregulatory index or Lax >0)
5.5. Duration of sedation
5.6. Percentage of patients that underwent Tier 3 therapies (decompressive craniectomy, hypothermia or metabolic suppression)
These clinical evaluations will last up to 1 week after the patient's study inclusion
5.7. Long-term neurological outcomes are measured by GOSE questionnaire collected at 6 months from the day of patient inclusion
6. Understanding of the study questionnaires measured by the percentage of questionnaires that were completed by the physicians at the end of the study period

Completion date
01/11/2027

Eligibility

Key inclusion criteria

1. Adult patients (age ≥18 years old)
2. Severe traumatic brain injury
3. Continuous invasive intraparenchymal ICP monitoring
4. Patient requires sedation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
105 Years

Sex
All

Total final enrolment
36

Key exclusion criteria
1. Do-not-resuscitate (DNR) order
2. Bilateral dilated pupils or absence of pupil reflection
3. Pregnancy
4. Known pre-existing neurocognitive disorders or brain dysfunctions
5. Known pre-existing spinal cord injuries with loss of motor function
6. Primary decompressive craniectomy

Date of first enrolment
01/02/2024

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
Belgium

Italy

Netherlands

Study participating centre
UZ Leuven
Herestraat 49
Leuven
Belgium
3000

Study participating centre
Maastricht UMC+
P. Debyelaan 25
Maastricht
Netherlands
6229 HX

Study participating centre
Radboud UMC
Geert Grooteplein 10, PO Box 9101
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Sponsor information

Organisation
Universitair Ziekenhuis Leuven

ROR
https://ror.org/0424bsv16

Funder(s)

Funder type
University/education

Funder Name
KU Leuven

Alternative Name(s)
Katholieke Universiteit Leuven

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Belgium

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository (K-drive, hosted by KULeuven).

IPD sharing plan summary
Stored in non-publicly available repository