ICU MANAGEMENT & PRACTICE

Recruiting centres for ICP monitoring study (SynapseICU)

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SYNAPSE-ICU An international prospective observational StudY on iNtrAcranial PreSsurE in intensive care (ICU), endorsed by the European Society of Intensive Care Medicine (ESICM), is now enrolling participant centres.

What is Synapse-ICU?

Intracranial pressure (ICP) monitoring is the most common neuromonitoring modality used in neurocritical care (NCCU) around the world. Uncertainties remain around ICP monitoring both in traumatic and non-traumatic brain injury, and variation in clinical practice of ICP monitoring exists between ICUs.

This project, initiated by the ESICM Neuro-Intensive Care Section is an international prospective observational study that will be conducted in several ICUs in different countries.

Why a study on intracranial pressure?

The recent Brain Trauma Foundation (BTF) Guidelines do not give clear indication on ICP monitoring because "there was insufficient evidence to support a Level I or II A recommendation for this topic".

The objectives of the study are to explore ICP monitoring variation (monitoring vs. non-monitoring) in practice in order to prioritise uncertainties in the clinical management of critical care patients with acute brain injury and support further collaborative hypotheses based prospective studies.

I manage severe acute brain damaged patients but I do not use ICP monitoring. Could I participate?

Sure. Centres inserting routinely ICP devices and centres not using it are both invited to participate.

How?

Methods

Sample Size: This international prospective observational study aims to recruit >5000 patients in coma after acute traumatic and non-traumatic brain damage admitted to >500 Intensive Care Units.

Inclusion Criteria:

- Admission to ICU following acute brain injury (ABI) in:

    - Haemorrhagic stroke, including:
        - intracerebral hematoma
        - subarachnoid haemorrhage;
    - Traumatic brain injury (penetrating and non-penetrating).
- Age >18 years old.
- Eye Opening of the Glasgow Coma Scale = 1 on admission to ICU or neuroworsening with no Eye opening in the first 48 hrs.
- Motor score of the Glasgow Coma Scale on admission to ICU <6 or neuroworsening with motor score decreased to <6 in the first 48 hrs.

Exclusion Criteria:

- Acute brain injury (ABI) not admitted to ICU.
- Other ABI (infective CSN disorders, ischemic stroke) not included in the inclusion criteria.
- Age < 18 years old.
- Eye opening on admission > 1 or Motor score of the Glasgow Coma Scale on admission to ICU = 6 without neuroworsening in the following 48 hours.

Outcome measures: Glasgow Outcome Scale-Extended at 3-6 months

Endpoint: The primary endpoint of the study is the exploration of the effect size of the variation in clinical practice around ICP monitoring in acute brain injury patients.

Duration of study

Screening and recruitment: 12 weeks at each centre (Aim 30 patients/centre. Ceiling to 30 patients/centre for each pathology).

Follow-up: outcome measures will be collected at 3-6 months.

Do I need IRB approval?

Centres prepared to participate must obtain approval of the local ethics committee or review board.

Is there any financial compensation?

No. Participation in the trial is completely voluntary.

How do I participate?

Register your interest here

Financial support

The project received support from ESICM after inclusion in the Trial Group portfolio.

Principal Investigator

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Documents

Protocol

Steering Committee

ClinicalTrials.gov registration

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