Early cessation of sedation and TTM in patients with a favourable EEG after cardiac arrest:
a feasibility and safety study

Published: 22-12-2023
Last updated: 02-12-2024

To estimate the feasibility and safety of early weaning from ICU treatment in patients after cardiac arrest and an early (< 12 h) favourable EEG pattern.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Encephalopathies
Study type	Interventional

Summary

ID

NL-OMON56493

Source
ToetsingOnline

Brief title
SELECT

Condition

- Encephalopathies

Synonym
cardiac arrest, Postanoxic encephalopathy

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Stichting Neurologisch Onderzoek Twente

Intervention

Keyword: Early cessation of sedation, EEG, Postanoxic encephalopathy

Outcome measures

Primary outcome

The primary outcome measure for the feasibility study will be the mechanical ventilation time in hours.

Secondary outcome

Secondary outcome measures will be:

Feasibility:

- Length of ICU stay (days).

- Need for re-intubation.

- Need for restarting sedation

Safety:

- Number of Serious Adverse Events (SAEs) at 30 days, 3 months, and 6 months.

- Mortality at 30 days, 3 months, and 6 months.

- Number of pneumonia, sepsis (according to sepsis 3 criteria), bleeding (any cause), cardiac arrhythmia (any associated with hemodynamic compromise), new cardiac arrest and thrombopenia.

Neurological functional outcome:

- Extended Glasgow Outcome Scale (GOSE) at 3 and 6 months.

- Cerebral Performance Category (CPC) at 3 and 6 months.

Cognitive functioning:

- Montreal Cognitive Assessment (MOCA) via videocall or telephone score at 3

and 6 months.

Patient experience of the deferred consent procedure:

- Short questionnaire at 3 months.

Study description

Background summary

Comatose patients after cardiac arrest are treated on intensive care units with sedative medication, targeted temperature management (TTM), mechanical ventilation, and hemodynamic support. Despite substantial variation in the severity of the encephalopathy and even lack of unequivocal evidence of efficacy of sedation and TTM, all patients receive standard treatment. The severity of the postanoxic encephalopathy can reliably be assessed with the electroencephalogram (EEG). A continuous EEG pattern within the first 12 hours after cardiac arrest (*favorable EEG*) is strongly associated with a good neurological outcome and reflects a very mild or transient encephalopathy. We hypothesize that this subgroup of patients, with a favorable EEG will not benefit from prolonged sedation and TTM.

Study objective

To estimate the feasibility and safety of early weaning from ICU treatment in patients after cardiac arrest and an early (< 12 h) favourable EEG pattern.

Study design

A non-randomized controlled intervention study with two treatment arms (early cessation from sedation and TTM vs standard care).

Intervention

The intervention contrast will be early cessation of sedation and TTM, with subsequent weaning from mechanical ventilation if appropriate (intervention group) vs. standard care, including sedation and TTM for at least 24-48 hours

(control group).

Study burden and risks

The safety of early cessation of sedation and TTM in patients with a favorable EEG directly after hospital admission (6-12 h after cardiac arrest), reflecting relatively mild, if any, postanoxic encephalopathy is unknown. There are diverse opinions on this topic. Some experts believe that anesthesia gives the brain *rest or silence" and thereby promotes recovery from ischemia, but this is not supported by any evidence and mechanisms of action are unclear. In contrast, other experts advocate that the risks of protraction of sedation and ventilation probably prevail in patients with spontaneous brain recovery according to the EEG, since shortening sedation and ventilation might prevent ICU-associated complications like pneumonia, circulatory compromise, and delirium impelling a longer ICU and hospital stay.

Besides the potential risks or benefits from early cessation or protraction of sedation and mechanical ventilation, the impact or burden of participating in the study is very limited. The EEG is made as part of routine care and no additional measurements are performed during the hospital stay. The follow-up consists of two video- or phonecalls of about 30 minutes.

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

- Patients after cardiac arrest admitted to the ICU for treatment with sedation, TTM and mechanical ventilation.
- Age 18 years or older.
- Continuous EEG measurement started within 12 hours after cardiac arrest.
- Favourable EEG pattern within 12 hours after arrest, defined as a continuous background pattern (NVN, 2019; Ruijter et al., 2019).
- Possibility to stop sedative treatment within three hours after identification of a favourable EEG pattern.
- Written informed consent (deferred).

Exclusion criteria

- A known history of another medical condition with limited life expectancy (<6 months).
- Any progressive brain illness, such as a brain tumour or neurodegenerative disease.
- Pre-admission Glasgow Outcome Scale Extended score of 4 or lower.
- Reason other than neurological condition to continue sedation and/or ventilation.
- Follow-up impossible due to logistic reasons.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-03-2024
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	22-12-2023
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NCT06048796
CCMO	NL84714.100.23