Treatment of electroencephalographic status epilepticus after cardiopulmonary resuscitation

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To estimate the effect of medical treatment of electro-encephalographic status epilepticus on neurological outcome of patients with postanoxic encephalopathy after cardiac arrest

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Encephalopathies
Study type	Interventional

Summary

ID

NL-OMON50403

Source
ToetsingOnline

Brief title
TELSTAR

Condition

- Encephalopathies

Synonym
epilepsy, ischemia

Research involving
Human

Sponsors and support

Primary sponsor: Ziekenhuis Rijnsate
Source(s) of monetary or material Support: Nationaal Epilepsie Fonds

Intervention

Keyword: antiepileptic drugs, EEG, postanoxic encephalopathy, status epilepticus

Outcome measures

Primary outcome

The primary outcome measure will be neurological outcome defined as the score on the Cerebral Performance Category (CPC) at 3 months dichotomized as good (CPC 1-2 = no or moderate neurological disability) and poor (CPC 3-5 = severe disability, coma, or death).

Secondary outcome

Secondary outcome measures will include i) mortality; ii) the CPC scores at 6 and 12 months; iii) length of stay on the ICU; iv) duration of mechanical ventilation; v) seizure recurrence within one year; vi) quality of life as measured by the Medical Outcomes Study 36-item short-form health survey (SF36) (Ware and Sherbourne, 1992), vii) depression as measured by the Montgomery and Åsberg Depression Rating Scale (MADRS) (Montgomery and Asberg, 1979), and viii) cognitive functioning as measured by detailed neuropsychological examination after 12 months.

Study description

Background summary

Electroencephalographic status epilepticus is described in 9-35% of patients with postanoxic encephalopathy after cardiac arrest and is associated with case fatality rates of 90-100%. It is unclear whether (some) electroencephalographic seizure patterns in these patients represent a condition which can be treated with antiepileptic drugs to improve outcome, or have to be regarded as an expression of severe ischemic damage, in which treatment with antiepileptic

would be futile. Therefore, both treatment with and treatment without antiepileptic drugs are considered standard treatment in these patients. We aim to compare these standard strategies and hypothesize that aggressive and early treatment of electro-encephalographic status epilepticus with antiepileptic drugs improves outcome as compared to treatment without these drugs.

Study objective

To estimate the effect of medical treatment of electro-encephalographic status epilepticus on neurological outcome of patients with postanoxic encephalopathy after cardiac arrest

Study design

We propose a multicenter clinical trial with randomized treatment allocation, open label treatment and blinded endpoint evaluation (PROBE design). The intervention contrast will be medical treatment vs. no treatment of electroencephalographic status epilepticus, in addition to standard best medical management of comatose patients after cardiac arrest, including therapeutic hypothermia.

Intervention

Treatment of electroencephalographic status epilepticus will be based on international guidelines for treatment of overt status epilepticus. The objective of the treatment will be to suppress all epileptiform activity in the EEG. If the electroencephalographic status epilepticus will return after tapering sedative treatment at 24 hours, the procedure will be repeated. If the status will return after 2 x 24 hours, it will be considered refractory.

Study burden and risks

Medical treatment of electroencephalographic status epilepticus may modify the high risk of death. Otherwise, treatment of electroencephalographic status epilepticus may lead to prolonged hospitalization of several days of comatose patients that otherwise would have died. The risk of an increase of morbidity or mortality on the longer term is negligible.

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 with suspected postanoxic encephalopathy
-Age 18 years or older
-Continuous EEG with at least eight electrodes started within 24 hours after cardiac arrest
-Electroencephalographic status epilepticus on continuous EEG*
-Possibility to start treatment within three hours after detection of electroencephalographic status epilepticus.
*We will use a broad definition of electroencephalographic status epilepticus, including all epileptiform discharges (spikes, poly spikes, sharp-waves, sharp-and-slow-wave complexes) at a rate of >= 0.5 Hz, irrespective of their spatiotemporal evolution, accompanying clinical phenomena, or effects of anti-epileptic drugs. Rhythmic delta or theta activity will not be included. For continuous seizure activity, the minimum duration requirement is 30 minutes. Intermittent seizures of 5 minutes and longer, recurring at least twice, with seizure-free intervals shorter than 60 minutes will also be included. EEG assessment for inclusion will be left to the discretion of the treating neurologist or clinical neurophysiologist.

Exclusion criteria

-A known history of another medical condition with limited life expectancy (<6 months)
-Any progressive brain illness, such as a brain tumor or neurodegenerative disease
-Pre-admission Glasgow Outcome Scale score of 3 or lower
-Reason other than neurological condition to withdraw treatment
-Follow-up impossible due to logistic reasons, for example not living in the Netherlands

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-05-2014
Enrollment:	167
Type:	Actual

Ethics review

Approved WMO

Date:	11-12-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	17-02-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-07-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-07-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-02-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-05-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-10-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-10-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-11-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United

	(Nieuwegein)
Approved WMO Date:	10-01-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-01-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-12-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-11-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-01-2021
Application type:	Amendment
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	NCT02056236
CCMO	NL46296.044.13

Study results

Date completed:	24-01-2022
Results posted:	04-03-2022
Actual enrolment:	171

Summary results
Trial is onging in other countries

First publication
24-02-2022