The Impact of Early Delirium Detection with DeltaScan on Management of Underlying Delirium Causes in Critically Ill Patients. A randomized controlled trial.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Deliria (incl confusion)
Study type	Interventional

Summary

ID

NL-OMON54010

Source
ToetsingOnline

Brief title
EARLY DELTA trial

Condition

- Deliria (incl confusion)

Synonym
confusion, Encephalopathy

Research involving
Human

Sponsors and support

Primary sponsor: HagaZiekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W,Prolira B.V.

Intervention

Keyword: Delirium, Deltascan, encephalopathy, intensive care

Outcome measures

Primary outcome

Primary endpoint is the ICU length of stay, which will be measured in hours.

Secondary outcome

Secondary endpoints observed during ICU stay:

delirium incidence, encephalopathy/delirium/coma-free days, cumulative dose of sedatives, opioids and antipsychotics, incidence of accidental removal of lines/tubes/drains by patient, incidence and duration of use of physical restraints, ventilator free days, organ support free days, ICU mortality

Secondary endpoints observed after ICU stay: ICU readmission, hospital length of stay, hospital mortality, 90 day mortality, 1 year self assessed quality of life, cognitive function, depressive symptoms and mobility/physical functioning.

Study description

Background summary

Delirium is an acute encephalopathy that manifests clinically as a disorder of attention, awareness and other cognitive functions. It is triggered by underlying somatic disorders and has a distinguishable electroencephalographic (EEG) signature known as polymorphic delta activity. In recent years, an MDR certified medical device, called Deltascan, has become available that can

detect the typical EEG changes seen in acute encephalopathy. Traditional clinical delirium screening instruments are known to have limited sensitivity, in particular for detecting hypoactive delirium. We hypothesize that adding EEG based encephalopathy detection to clinical observation scales increases the sensitivity and results in earlier detection of delirium and subsyndromal delirium, resulting in improved clinical outcomes of critically ill patients, such as delirium duration, ICU length of stay or survival.

Study objective

This randomized controlled trial aims to study the effect of implementation of EEG based encephalopathy detection (DeltaScan, Prolira, Utrecht, The Netherlands, hereafter: DeltaScan) on relevant clinical endpoints (ICU length of stay) as well as the effect on delirium management decision by ICU staff, in a mixed medical and surgical intensive care unit population that is typical for Western European hospitals.

Study design

This studiy is a randomized controlled trial, where patients are assigned to either an intervention group or a control group. Control group recieves usual care, where the patients* medical team obtains regular delirium screening. The intervention group recieves usual care plus twice daily DeltaScan measurements. During the daily medical rounds, the DeltaScan results will be presented to the patients* medical team together with decision support, consisting of DeltaScan trend interpretation and protocol-based suggestions for evaluation of underlying delirium cause.
In the control group, a team of researchers will obtain DeltaScan measurements twice daily. These measurements will only be recorded in the electronic case record form (eCRF), but not in the patients* electronic medical records.
Because DeltaScan may detect encephalopathy before clinical symptoms emerge, it is necessary to obtain DeltaScan measurements in both groups, to avoid a false comparison of delirium duration between the groups. In patients only followed with *usual care*, encephalopathy / delirium could potentially be detected later or not at all compared to when DeltaScan would be used. This could result in falsely increased delirium duration in patients who undergo DeltaScan measurements.

Intervention

In the intervention group, the DeltaScan measurement result will be visually presented to the medical team in the patient data management system (PDMS), during daily medical rounds. PDMS then suggests appropriate diagnostic or therapeutic interventions, based on the measurements and the department's delirium protocol.

To make fair comparisons between the groups, the study team will also measure patients in the control group with DeltaScan twice daily, but will not disclose the result to the patients' medical team. Also, PDMS will not show decision support suggestions. This prevents unwanted effects of the DeltaScan measurements on the control subjects' medical treatment. The medical team will use daily clinical routines, based on the department's delirium protocol.

This method ensures a proper comparison of delirium incidence and - duration between groups, without bleed-over of the potential effect of the DeltaScan measurements to the control group (routine care). This method also enables us to analyse the effect of DeltaScan on decisions made by the patients' medical team regarding diagnostic interventions to detect underlying causes of delirium.

Study burden and risks

In this study, it is not expected that randomization to the intervention group adds risk for patients. This is a study of a diagnostic intervention with additional encephalopathy/delirium observations consisting of a short (90 seconds) EEG measurement, which does not harm the patient. Clinicians will receive protocol-based decision support alongside the diagnostic observation. No additional medical treatments will be conducted as part of the study protocol.

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

Adult (18 years or above) patient admitted to the intensive care unit
ICU length of stay anticipated to be 48h or longer from time of inclusion
Written informed consent by patient or representative

Exclusion criteria

- More than 48 hours have elapsed since the patient was first eligible to undergo a DeltaScan measurement after ICU admission. (A patient is eligible for DeltaScan measurements if they are a. able to cooperate with simple instructions AND b. are alert or mildly sedated no deeper than a Richmond Agitation and Sedation Score (RASS) of -2.) Admission for * -out-of-hospital cardiac arrest* -status epilepticus* -hemorrhagic or ischemic stroke* -increased intracranial pressure -head trauma Recent intracranial neurosurgery (<30 days prior to inclusion) Known space-occupying lesions in the brain or skull Metal implants in brain or skull Diagnosis of dementia or Parkinson*s disease Inpatient from nursing home Lithium use (<30 days prior to inclusion) Imminent death or palliative care phase Patients and their legal representatives both do not understand Dutch or English Participation in the EARLY DELTRA trial <90 days ago

Study design

Design

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

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-03-2022
Enrollment:	290
Type:	Actual

Medical products/devices used

Generic name:	Deltascan
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	16-12-2021
Application type:	First submission
Review commission:	METC NedMec

Approved WMO

Date:	02-05-2022
Application type:	Amendment
Review commission:	METC NedMec

Approved WMO

Date:	15-02-2023
Application type:	Amendment
Review commission:	METC NedMec

Approved WMO

Date:	18-07-2023
Application type:	Amendment
Review commission:	METC NedMec

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	NCT05403268
CCMO	NL78854.041.21