Improving patient care through early and objective detection of delirium for geriatric trauma patients in a trauma geriatric center

Published: 25-05-2021
Last updated: 04-07-2024

To quantify the impact of the use of DeltaScan on patient outcome (duration of admission) in patients with high risk of delirium compared to the currently used delirium screening tools.

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

Summary

ID

NL-OMON54243

Source
ToetsingOnline

Brief title
DeltaScan in geriatric trauma patients

Condition

- Other condition

Synonym
Delirium

Health condition

cognitieve aandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Onderzoeksfonds St. Antoniusziekenhuis

Intervention

Keyword: delirium, detection, Geriatric, trauma

Outcome measures

Primary outcome

Primary endpoints: duration of admission at trauma geriatric department (length of stay)

Secondary outcome

Secondary endpoints: time interval between admission and the first delirium positive assessment, number of days with at least one positive delirium assessment, delirium incidence, hospital mortality, and direct medical costs of hospitalization.

Study description

Background summary

Delirium, or acute brain failure, presents as an acute confusional state, and is associated with prolonged hospitalization, increased risk of dementia, institutionalization and mortality, ultimately resulting in burden of disease and an increase of costs. Early detection of delirium would allow for early treatment and could improve patient outcomes, but delirium is often not recognized and treatment is therefore delayed or not applied at all. Additionally, current screening tools are subjective, so an alternative, more objective diagnostic tool for early delirium detection is desired. The DeltaScan, a CE-certified device to detect delirium using brief electro-encephalography (EEG) recording, appears to have diagnostic properties that outperform currently used screening tools.

Study objective

To quantify the impact of the use of DeltaScan on patient outcome (duration of admission) in patients with high risk of delirium compared to the currently used delirium screening tools.

Study design

Single blinded randomized trial, total included persons 388.
194 patients intervention group, 1194 patients control group (regular delirium screening) randomly allocated with REDCap.

Intervention

DeltaScan, EEG scan for 2 minutes / 2 times a day

Study burden and risks

During the intervention period EEG recordings using the CE-certified DeltaScan will be made using a strip with EEG electrodes that will be mounted to the head using self-adhesive gel. The EEG recording will be performed two times daily and will take 2 minutes. During the usual care period patients will receive the standard delirium
screening tool for delirium assessment by a nurse. This assessment will be performed two times daily and take 2 minutes. Based on the above we consider the burden to participants in this study to be minimal.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

Patient admitted to our hospital with a hipfracture > 70 years

Exclusion criteria

• Acute macro brain injury in 6 weeks prior to the DeltaScan measurement (such as traumatic brain injury).
• Admitted because of a primary neurological or neurosurgical disease or postanoxic encephalopathy
Patients who cannot clinically be assessed for delirium, e.g. due to a language barrier or deafness.
• Patients using lithium or Clozapine
• Patients with a metal plate or a metal device in the head
• Known pre-existing dementia.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-08-2021
Enrollment:	388
Type:	Actual

Medical products/devices used

Generic name:	DeltaScan
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	25-05-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-03-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-06-2023
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	NCT03735940(trial1)&NCT03735927(trial2)
CCMO	NL76875.100.21