Brain ProTCT: Deltascan vs DOSS after cardiac surgery

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27069

Source
Nationaal Trial Register

Brief title
Brain ProTCT

Health condition

Heart diseases

Sponsors and support

Primary sponsor: MST Tthoraxcentrum Twente
Source(s) of monetary or material Support: Part of the costs for this study will be covered by Stichting Hartcentrum Twente. Prolira trains staff free of charge; provides the DeltaScans during the study period free of charge and applies a discount to the disposable patch costs. Prolira has no influence on the study design, data collection, data analysis or interpretation, writing scientific papers or the decision to submit such a paper.

Intervention

Outcome measures

Primary outcome

Two primary endpints: Length of hospital stay after cardiac surgery, and incidence of

detected delirium at the surgical ward

Secondary outcome

Hospital readmissions within 30 days after surgery; hospital-related costs related to delirium diagnosis, treatment of delirium and screening for underlying causes for delirium, and costs for hospital stay; ICU length of stay (hours), discharge location, hospital- and 30-day mortality, delirium duration, Netherlands Heart Registry in-hospital endpoints for cardiac surgery, adherence to delirium protocol

Study description

Background summary

Delirium is a serious and common neuropsychiatric disorder (American Psychiatric Association, 2013) that is related to adverse long-term outcomes (Inouye, Westendorp, & Saczynski, 2014a). Postoperative delirium occurs often in hospitalized older patients following cardiac surgery, with an incidence in the postoperative period of 17% (including elective patients aged ≥45 years, (Koster, Hensens, Schuurmans, & Van Der Palen, 2012) and 13% (including elective adult patients,(ten Broeke, Koster, Konings, Hensens, & van der Palen, 2018)) respectively. Early detection of delirium enables early treatment of the underlying cause. Therefore, screening for delirium in patients at risk is an important part of clinical follow-up after surgery (Inouye, Westendorp, & Saczynski, 2014b; Marcantonio, 2017a; Nederlandse Vereniging voor Klinische Geriatrie, 2013; Samuel et al., 2015)
Although delirium screening is part of routine practice following cardiac surgery, patients with a hypoactive or mixed form of delirium are possibly missed (Marcantonio, 2017b). Current screening methods, such as the DOSS, are subjective. Although the DOSS is a sensitive instrument in research settings, during care-as-usual the sensitivity may decrease to 32% (Numan et al., 2017).
Recently, an objective medical device has been developed that can detect delirium based on a short one-channel EEG measurement: DeltaScan (Numan et al., 2019). Using DeltaScan in routine care may improve the delirium detection (Numan et al., 2019). Furthermore, improved detection of delirium may lead to improved patient outcomes such as length of stay and therefore to reduced hospital costs (Gleason et al., 2015; Lundstrom et al, 2005; Young & George, 2003).

In the present study, we aim to assess whether introduction of DeltaScan in routine clinical care as screening instrument for delirium, will (1) increase the reported incidence of delirium in the postoperative period, and (2) reduce hospital stay of delirious patients in the postoperative period at Thoraxcentrum Twente (TCT).

Study objective

The use of DeltaScan for delirium screening reduces length of hospital stay and increase the

detection of delirium, in comparison with the Delirium Observation Scale

Study design

Surgical ward; 30-days after surgery

Intervention

Patients are screend for delirium with DeltaScan or the Delirium Observation Scale. The treatment of delirium is identical, and is according to hospital protocols.

Contacts

Public
Medisch Spectrum Twente - Thoraxcentrum Twente
Frank Halfwerk

0534872105
Scientific
Medisch Spectrum Twente - Thoraxcentrum Twente
Frank Halfwerk

0534872105

Eligibility criteria

Inclusion criteria

Patients over 70 years of age who received cardiac surgery (including TAVI patients with a thoracotomy) in the MST Thoraxcentrum Twente

Exclusion criteria

Patients who use lithium, have metal cranial implants, have dementia or other diseases that influence EEG measurements (i.e. acute brain damage) are excluded, because these are contraindications for DeltaScan use. Patients who opted-out of this study will be excluded as well.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-04-2021
Enrollment:	788
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
The IPD might be shared according to FAIR principles in the 4TU database.

Ethics review

Positive opinion

Date:	21-04-2021
Application type:	First submission

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
NTR-new	NL9435
Other	METC Twente : K20-58

Study results