Brain ProTCT: Deltascan vs DOSS after cardiac surgery

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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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27069

Bron
NTR

Verkorte titel
Brain ProTCT

Aandoening

Heart diseases

Ondersteuning

Primaire sponsor: MST Tthoraxcentrum Twente
Overige ondersteuning: 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.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Two primary endpints: Length of hospital stay after cardiac surgery, and incidence of detected delirium at the surgical ward

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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

Onderzoeksopzet

Surgical ward; 30-days after surgery

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	12-04-2021
Aantal proefpersonen:	788
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

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

Ethische beoordeling

Positief advies

Datum:	21-04-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9435
Ander register	METC Twente : K20-58

Resultaten