Observational study on the predictive value of the BAMCOG and cortisol levels for the incidence of Postoperative Delirium/Postoperative acute encephalopathy measured by the MoCA and the DeltaScan in patients who undergo Aortic Valve Replacement surgery

Published: 17-08-2021
Last updated: 05-04-2024

1. The predictive value of the BAMCOG for developing postoperative delirium/postoperative acute encephalopathy in patients who underwent AVR surgery2. Concurrent validation of the BAMCOG with the MoCA3. The relation between cortisol levels in blood...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Deliria (incl confusion)
Study type	Observational non invasive

Summary

ID

NL-OMON49940

Source
ToetsingOnline

Brief title
The prediction of POD by the BAMCOG and cortisol levels

Condition

- Deliria (incl confusion)

Synonym
Popsoperative delirium, postoperative confusion

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Stichting Anesthesiologie/Stichting Intensive Care

Intervention

Keyword: Aortic Valve Replacement, Cognitive dysfunction, Delirium, Predictive value

Outcome measures

Primary outcome

We are going to investigate the prognostic value of the BAMCOG for the

development of postoperative acute encephalopathy in patients undergoing AVR

surgery.

Secondary outcome

a. The correlation between the BAMCOG-scores and the MoCA-scores

b. The prognostic value of diverse cortisol measurements (blood, sweat, saliva)

in the prediction of postoperative acute encephalopathy in patients undergoing

AVR surgery.

Study description

Background summary

The mean age of surgical patients is rising worldwide and this is associated with more multi-morbidity. Especially geriatric patients who undergo surgery have a higher risk to develop Postoperative Cognitive Dysfunction or a Postoperative Delirium, which leads to higher morbidity and mortality after

surgery and this leads to higher healthcare costs.

A delirium is an acutely disturbed state of mind characterized by restlessness, illusions, and incoherence, occurring in intoxication, fever, and other disorders and can fluctuate over time. The hypoactive delirium, the most common type of delirium, is hard to recognize compared to the active delirium that is expressed by restlessness and agitation.

Postoperative cognitive dysfunction is defined as a new cognitive impairment arising after a surgical procedure. Its diagnosis requires both pre- and postoperative psychometric testing. Its manifestations are subtle and manifold, depending on the particular cognitive domains that are affected, and therefore hard to recognize too.

To assess preoperative cognitive function in large groups of patients, we need a simple and quick tool to screen. In this study, we use the BAMCOG, which is a tool with 3 short games played on a tablet that can give us information about cognitive functioning. When writing this new study protocol, a validation study in which the BAMCOG is validated against the MoCA is running.

Beside the BAMCOG, another instrument will be investigated. The DeltaScan is an EEG delta waves measurement to identify patients with a (hypoactive) delirium. Delta waves are slow brainwaves that have been seen in sedated patients and even in patients with an active or hypoactive delirium. A study of Kimchi et al. studied whether routine clinical EEG findings, including slowing, are correlated with delirium severity in a heteroge- neous population with various causes ofaltered mental status and found that generalized slowing on routine clinical EEG strongly correlates with delirium and may be a valuable biomarker for delirium severity (OR 7.4, 95% CI 3.8-14.4).

A lot remains unclear about the biological mechanisms in the development of a delirium after surgery, although in literature are directions that inflammatory reactions and the neuro-endocrine system play an importante role. That is the reason for investigating the relation between cortisole levels in blood, saliva and sweat and the development of postoperative acute encephalopathy.

Study objective

1. The predictive value of the BAMCOG for developing postoperative delirium/postoperative acute encephalopathy in patients who underwent AVR surgery
2. Concurrent validation of the BAMCOG with the MoCA
3. The relation between cortisol levels in blood, saliva and sweat and the development of postoperative delirium/postoperative acute encephalopathy.

Study design

Measurements

Preoperative:
At the outpatient clinic: BAMCOG, MoCA and DeltaScan
At home: 2 saliva tests
Time: 1 hour.

Day of surgery:
Sweat, saliva and blood sample (2x/day)

Postoperative:
Day 1, 3 and 7 after surgery: BAMOG, MoCA, DOS score (Delirium Observation Score) and DeltaScan (3x/day)

Extra time per day: 1 hour
Total extra time: 4 hours (of which 3 days in hospital after surgery)

Study burden and risks

There are no relevant risks associated with participation on this study except extra time load.

Contacts

Public
Catharina-ziekenhuis

Michelangelolaan 2
Eindhoven 5623EJ
NL
Scientific
Catharina-ziekenhuis

Michelangelolaan 2
Eindhoven 5623EJ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

65 years or older
Scheduled for an AVR surgery
Capable of playing the BAMCOG after instruction
Near native Dutch speaker

Exclusion criteria

Mental disorder
Learning disorder
Alcohol abuse
Medication use: clozapine or lithium
Not capable of signing informed consent
Patients with an implanted device, such as a defibrillator, neurostimulator, pacemaker, or ECG monitor.
Patients with a history of epilepsy or seizures.
Patients who are pregnant.
Patients that have a known sensitivity or allergy to any ingredient.
Over damaged, denuded skin or other recent scar tissue.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	18-01-2022
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	17-08-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-12-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-12-2021
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
CCMO	NL78313.100.21