Piloting the effect of transcranial direct current stimulation(tDCS) in the prevention and treatment of delirium in patients undergoing cardiothoracal surgery

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Primary Objective: Testing the efficacy of tDCS as a 7 day add-on prevention in patients electively admitted to the ICU after cardiothoracic surgery on top of usual clinical care by measuring the change in delirium symptoms.Secondary Objective(s):...

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

Summary

ID

NL-OMON51005

Source
ToetsingOnline

Brief title
tDCS in delirium patients

Condition

- Deliria (incl confusion)

Synonym
confusion, delirium

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cardiothoracic patients, delirium, IC, tDCS

Outcome measures

Primary outcome

Efficacy to use tDCS as preventive treatment for delirioum (as measured with clinical scales) in patients admitted to the ICU electively or acutely after cardiothoracic surgery. tDCS is applied on top of routine clinical care.

Secondary outcome

- Cognitive symptoms at baseline in elective patients and after one week intervention will be assessed by the Montreal Cognitive Assessment Scale (MOCA, for a direct comparison also with the Mini mental state examination see Saczynsky et al., 2016).
- Effect on incidence of delirium and delirium symptoms will be compared with a comparable anonymized dataset of cardiothoracic patients matched on age and co-morbidity (Charlson Index).
- Feasibility to apply tDCS in patients that develop delirium.
- Moreover feasibility is measured defined as the degree to which tDCS sessions are completed. Also, patients and tDCS staff will use a 5-point Likert scale to answer questions about practicality and burden.

Study description

Background summary

Delirium affects 20-30% of patients after cardiac surgery and is associated with deleterious short term outcome and persistent cognitive decline. Delirium signs may evolve already during postoperative stay of these patients on the intensive care unit (ICU). Prevention of delirium post-cardiac surgery has proven to be problematic. Non-pharmacological interventions to prevent delirium on the ICU in post-cardiac surgery patients are limited as patients are often elderly, deeply sedated, with multi-morbidity and polypharmacy. Pharmacological treatment of delirium in ICU patients (antipsychotics, benzodiazepines) did not proof to be effective.
Non-invasive brain stimulation in the form of transcranial direct current stimulation (tDCS) has shown to alter brain oscillations thereby improving neurocognitive capacity as can be measured in performance in attention, memory and executive function. Currently tDCS is widely tested as add-on treatment option in the field of neuropsychiatric rehabilitation. It seems therefore worthwhile to investigate the feasibility and potential efficacy of tDCS in ICU patients after cardiac surgery as tDCS is an non-invasive, painless and easy to perform method of treatment witch modulates EEG patterns and hopefully prevents or ameliorates the occurrence and course of delirium .

Study objective

Primary Objective: Testing the efficacy of tDCS as a 7 day add-on prevention in patients electively admitted to the ICU after cardiothoracic surgery on top of usual clinical care by measuring the change in delirium symptoms.
Secondary Objective(s): change in cognitive symptoms one week after intervention. Feasibility reports of patients, ICU nurses and trained member of the consultation psychiatry team (MP/IT or trained nurse).

Study design

Pilot open label study whereby 20 patients undergoing cardiothoracic surgery including postoperative care at the ICU will receive an anodal treatment (anodal electrode over left dorsolateral prefrontal cortex (DLPFC)) with tDCS on 7 consecutive days , starting 1 or two days after the operation (depending on the level of sedation). tDCS will be given by a medical specialist trained in neuromodulation (IT/MP) who is supported by a nurse from the consultation psychiatry service and a master student neuroscience. tDCS treatment will be started at the ICU and continued at the ward where patients are usually referred to,after three days. Treatment will be continued independent of absence or presence of delirium symptoms. Delirium treatment will be performed as usual. Change in delirium symptoms will be assessed with the intensive care

delirium checklist (ICDSC) on/at ? the ICU and the delirium observation scale (DOS) on/at? the ward, during the cause of 10 days and the Montreal Cognitive Assessment Scale (MOCA) will be assessed prior to surgery (if possible) and after 7 days of tdcs treatment.

Intervention

Patients will receive a seven day stimulation (DC-Stimulator, NeuroConn GmbH, Germany) consisting of 2 mA tDCS delivered for 20 minutes using a pair of electrodes with conductive paste (surface 35 cm2, current density ±0.03 mA/cm2). The anode will be placed over the left dorsolateral prefrontal cortex. The cathode will be placed over the right supraorbital area.

Study burden and risks

tDCS is a widely used non-invasive neuromodulation technique, applying weak direct currents through conductive rubber/sponge electrodes to the scalp. These weak currents can slightly shift the neurons* membrane potential and thereby modulate spontaneous neuronal activity in the stimulated cortex. During stimulation, participants may transiently experience light tingling or itching sensations on the skin underlying the electrodes. which can be unpleasant. The most common side-effects are a light transient headache and a feeling of fatigue. The conventional tDCS protocol proposed here is considered safe according to the latest published international safety guidelines. All participants are screened for their relevant medical history and other tDCS safety aspects (e.g. metal parts in the head, skin allergies). In summary, the tDCS risk is negligible, the burden associated with participation can be considered minimal, and no serious adverse events are expected during this study as a result of the tDCS intervention. Patients can withdraw from the study at any time. Delirium is a burden for patient and family of the patient and particular at the ICU effective treatment is a matter of debate. Even small improvements in prevention of treatment of delirium will therefore have large clinical and societal impact.

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

Admitted acutely or electively to the adult ICU of the Radboudumc following cardiothoracic surgery. From this group, we suggest to only select the cardiothoracic surgery adult patients with the highest incidence of post-operative delirium (30-50%). These include those that undergo the following types of surgery: all aortic surgery, CABG combined with valve surgery, double valve surgery.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

History of dementia
Inability to conduct valid delirium screening assessment (e.g. coma, deaf, blind, severe polyneuropathy or myopathy) or inability to speak the Dutch language.
Epilepsy
Known pre-existing dementia
Standard contra-indications for tDCS, including:
History of serious head trauma or brain surgery
Large or ferromagnetic metal parts in the head (except for a dental wire)
Implanted cardiac pacemaker or neurostimulator

Skin diseases at intended electrode sites
Expected to die within 24*hours.

On top of these exclusion criteria, there are specific reasons why a tDCS session cannot be performed, including:
* RASS score of -3 or lower
* Severe agitation (RASS >+2)

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	08-06-2021
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	12-05-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL76704.091.21

Study results

Date completed: 31-05-2022

Results posted: 04-09-2022

Summary results
Trial ended prematurely

First publication
17-08-2022