MusiC to prevent deliriUm during neuroSurgerY

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22786

Source
Nationaal Trial Register

Brief title
MUSYC

Health condition

Delirium.

Sponsors and support

Primary sponsor: Erasmus MC Doelmatigheid 2019
Source(s) of monetary or material Support: Mrace Erasmus MC

Intervention

Outcome measures

Primary outcome

The primary outcome measure is presence or absence of postoperative delirium within the first 5 days after surgery.

All participating patients on the ward will be screened using the Delirium Observation Screening (DOS) scale. Additional to the DOS, in case of raised suspicion of delirium, a

psychiatrist is consulted to confirm or reject clinical diagnosis of delirium based on the DSM-V criteria.

Secondary outcome

- Severity and duration of delirium.
- Pre-operative anxiety.
- Activation of the parasympathetic nervous system measured with HRV.
- Depth of anaesthesia registered with Bispectral Index (BIS).
- Peri-operative medication use.
- Postoperative pain.
- Postoperative complications.
- Hospital length of stay in days.
- Cognitive function.
- Daily function, expressed in Karnofsky Perfomance Scale (KPS) and Modified Ranking Scale (mRS).
- Mortality and readmission rate.
- Health-related quality of life
- Patient satisfaction.
- Economic evaluation. An evaluation of the costs and cost-effectiveness of the intervention will be made. See section 10.3.

Study description

Background summary

Rationale:
Delirium is a common and severe complication after neurosurgical procedures. Music before, during and after surgical procedures has proven its effectiveness in reducing pain, anxiety, stress and opioid medication in surgical patients. These symptoms belong to the main eliciting factors for developing delirium. Effective preventive therapy for delirium is not available. We hypothesize that music listening, being a sustainable intervention with negligible risk of side effects, can lower delirium incidence among neurosurgical patients, resulting in reduction of in-hospital stays, healthcare costs and post-operative morbidity and mortality.

Objective:
To assess the effect of peri-operative music on post-operative delirium in patients undergoing a craniotomy.

Study design:
Single-centre prospective randomized controlled trial.

Study population:

Adult patients undergoing a craniotomy at the Erasmus MC in Rotterdam.

Intervention:
Recorded music, with headphones or earbuds, before, during and after surgery.

Main study parameters/endpoints:
Diagnosis of post-operative delirium screened by the DOS score confirmed by the consultant psychiatrist following the DSM-V criteria.

Study objective

We expect an incidence of delirium in our control group of 30%. This is based on literature documenting incidence of delirium in neurosurgical patients in a northern European population of 29-33%.

The expected effect cannot be based on previous literature since no adequate trials exist on the effect of music on delirium. Other non-pharmacological interventions mention a relative reduction of 36-77%. We will consider the intervention clinical relevant if a relative reduction of 60% with an absolute reduction of 18% is achieved.

Study design

T0: inclusion, T1: intervention during admission, T2: 6 weeks follow-up, T3: 3 months follow-up, T4: 6 months follow-up

Intervention

Patients will be randomly allocated to either the intervention (music) or control (standard care) group.

Participants in the music group will receive headphones with music 30 minutes before surgery. Patients will be able to choose music from a preselected list composed by a team consisting of researchers and dedicated music therapists. The headphones will be removed just before entering the operating room. Once in the operating room they will receive earbuds after intubation, compatible with the Mayfield and site of operation. The intraoperative music intervention will be continued during the surgical procedure and discontinued just before detubation. The duration of the intraoperative music intervention depends on the duration of
surgery and will be documented. After surgery, during recovery at the post-operative care unit (PACU) another 30 minutes of music through headphones will be given. The following 3 days at the neurosurgical ward they will receive music twice a day for 30 minutes.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients undergoing a craniotomy.
2. Adult patients (cq age ≥18 years)
3. Sufficient knowledge of the Dutch language to understand the study documents in the judgement of the attending physician or researcher.
4. Provision of written informed consent by patient or legal representative.

Exclusion criteria

1. Impaired awareness before surgery (i.e. GCS < M6).
2. Planned post-operative ICU admission.
3. Suspected delirium (defined as fluctuating awareness).
4. Current antipsychotic treatment.
5. Patients undergoing interventions impeding supply of music (e.g. surgical translabyrinthine approach, awake surgery).
6. Severe bilateral hearing impairment, defined as no verbal communication possible.
7. Current participation in other clinical trials interfering with results.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	09-07-2020
Enrollment:	189
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
Data Sharing statements according to ICMJE Guidelines. Individual participant data will be available. This includes data that underlie the results reported in this article, after de-identification (text, tables, figures and appendices). Other documents such as Study Protocol, Statistical Analysis plan, Informed Consent form, Clinical Study Report and Analytical Code will be made available. This will be made available to researchers, which need it to approve their proposal or for meta-analysis, which request data after providing a methodologically sound proposal beginning 3 months until 5 years after article publication. Proposals should be directed to p.kappen@erasmusmc.nl. To gain access, data requestors will need to sign a data access agreement.

Ethics review

Positive opinion

Date:	04-04-2020
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	NL8503
Other	METC EMC : MEC-2020-0064

Study results

Summary results
N/A