Intraoperative Music to PROMote PaTient oUtcome (IMPROMPTU): a double-blind, placebo-controlled, randomized multicenter trial

No registrations found.

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

Summary

ID

NL-OMON23998

Source
NTR

Brief title
IMPROMPTU

Health condition

Esophageal cancer, Esophagectomy, gastric cancer, gastrectomy, music, perioperative patient care, stress response to surgery.

Slokdarmkanker, slokdarmresectie, maagkanker, maagresectie, muziek, perioperatieve patientenzorg, chirurgische stress respons

Sponsors and support

Primary sponsor: Erasmus MC, University Medical Center Rotterdam
Source(s) of monetary or material Support: Muziek als Medicijn Foundation (www.muziekalsmedicijn.nl)

Intervention

Outcome measures

Primary outcome

The primary outcome is postoperative pain (Numeric Rating Scale (NRS)).

Secondary outcome

Secondary outcomes are intraoperative medication requirement (intraoperative propofol, opioids and catecholamines), postoperative opioid requirement, stress response to surgery (serum cortisol, tumor necrosis factor alpha (TNF-α), interleukin-6 (IL-6), C-reactive protein (CRP)), intraoperative vital parameters, postoperative complications, hospital length of stay and 30-day mortality.

Study description

Background summary

Perioperative music has a significant beneficial effect on postoperative pain and anxiety, possibly through attenuation of the stress response to surgery. This beneficial effect can still be observed when music is played solely during general anaesthesia, since auditory sensory information is processed by the brain even under deep sedation. High pain levels and a more vigorous stress response after surgery have a negative impact on patient outcome. This study will investigate the effect of intraoperative music in patients undergoing surgery for esophageal or stomach cancer under general anaesthesia.

The main objective of this study is to investigate whether intraoperative music reduces postoperative pain in patients undergoing surgery for esophageal or stomach cancer. Secondary objectives are the effects of intraoperative music on medication requirement, stress response to surgery, intraoperative vital parameters, postoperative complications, hospital length of stay and 30-day mortality.

Study objective

Perioperative music has a significant beneficial effect on postoperative pain, which can even be observed when music is played solely during general anaesthesia since auditory sensory information is processed by the brain under deep sedation. Perioperative music also attenuates the physiological stress response to surgery.

The study hypothesis is that the beneficial effect of music on postoperative pain and the stress response to surgery will improve patient clinical outcome by reducing postoperative complications and hospital length of stay.

Study design

Surgery and intraoperative music intervention
30-day follow-up (electronic patient database)

Intervention

Patients will be randomly allocated to one of two study arms. The intervention group will receive intraoperative music as an intervention; the control group will not hear music. All participants will wear headphones during surgery. The music intervention will consist of a preselected playlist of music based on recommendations of literature.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
1. Patients undergoing elective surgical esophageal or stomach cancer resection
2. Age ≥ 18 years
3. Provision of written informed consent by the patient

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
1. Patients using systemic steroid, immunosuppressant or cytotoxic medication at the moment of music intervention
2. Known hearing impairment or use of an hearing aid
3. Insufficient knowledge of the Dutch language to understand the study documents in the judgement of the attending physician or researcher
4. Objection to any unknown music
5. Patients with locally advanced, unresectable esophageal or stomach cancer

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2018
Enrollment:	70
Type:	Anticipated

Ethics review

Positive opinion

Date:	10-10-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48702
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7330
NTR-old	NTR7546
CCMO	NL64875.078.18
OMON	NL-OMON48702

Study results