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

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON48702

Source
ToetsingOnline

Brief title
IMPROMPTU

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal therapeutic procedures

Synonym
esophageal and gastric cancer surgery, gullet and stomach cancer surgery

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Muziek als Medicijn Foundation

Intervention

Keyword: Esophageal cancer surgery, Gastric cancer surgery, Music, Stress response

Outcome measures

Primary outcome

Postoperative pain (NRS)

Secondary outcome

- Intraoperative medication requirement

- Postoperative opioid requirement

- Stress response to surgery (serum total cortisol, tumor necrosis factor alpha

(TNF-*), interleukin-6 (IL-6) and C-reactive protein (CRP))

- Postoperative complications

- Hospital length of stay

- 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.

Study objective

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 intraoperative medication requirement, postoperative opioid requirement, stress response to surgery, intraoperative vital parameters, postoperative complications, hospital length of stay and 30-day mortality.

Study design

Double-blind, placebo-controlled, randomized multicenter trial

Intervention

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 and experts.

Study burden and risks

Music has no known deleterious effects. A lock on the music volume will be installed to limit the music volume. Part of the measurements and data collection is embedded in standard surgical care, and part will be collected for study purposes, consisting of two blood samples and one 4-item questionnaire. No additional hospital visits are necessary for this study. This study will be performed in patients with esophageal or stomach cancer, in which surgical treatment is associated with high morbidity and mortality, and reducing postoperative pain and the stress response to surgery may lead to a decrease in postoperative complications and hospital length of stay. Overall, the burden and risks associated with the intervention in this study are negligible.

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

1. Patients undergoing elective esophageal or stomach cancer surgery
2. Age * 18 years
3. Provision of written informed consent by the patient

Exclusion criteria

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
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-11-2018
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	19-07-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	03-01-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-03-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 23998
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL64875.078.18
OMON	NL-OMON23998