

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

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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....

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23998

Bron

NTR

Verkorte titel

IMPROMPTU

Aandoening

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

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

Ondersteuning

Primaire sponsor: Erasmus MC, University Medical Center Rotterdam

Overige ondersteuning: Muziek als Medicijn Foundation (www.muziekalsmedicijn.nl)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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 $\geq$ 18 years
3. Provision of written informed consent by the patient

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-10-2018
Aantal proefpersonen:	70
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	10-10-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48702

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten