Music interventions in operative treatment of funnel chest

Gepubliceerd: 22-02-2018 Laatst bijgewerkt: 18-08-2022

Music interventions will reduce anxiety and pain in patients undergoing a nuss bar procedure due to pectus excavatum

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

Samenvatting

ID

NL-OMON22918

Bron
Nationaal Trial Register

Verkorte titel
IMPECT

Aandoening

Pectus excavatum

Ondersteuning

Primaire sponsor: University Medical Center
Overige ondersteuning: Erasmus University Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Main parameter is the experienced level of pain, assessed with self-report on the Visual Analogue Scale (VAS) expressed in millimetres.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: This study will investigate the effects of listening to a recorded music intervention prior, during and after surgical pectus excavatum treatment. Multiple studies have found music interventions may reduce post-operative pain, anxiety and distress in patients undergoing a surgical procedure. Since surgical pectus excavatum treatment is a highly painful as well as distressing procedure, this durable non-toxic method could be a welcome intervention. In this study, we will investigate the hypothesis that music interventions prior, during and after pectus excavatum surgery will result in less postoperative pain and distress.
Objective: The main objective of this study is to investigate the role of recorded music prior, during and after surgery as an additive treatment modality in reducing the level of pain. Secondary objectives are effects of music on the use of analgesics, on anxiety and distress, vital parameters, minor postoperative complications, quality of life and care-costs.
Study design: This study will be performed as a parallel randomised controlled intervention trial.
Study population: The research will take place in patients in the age of 12 to 18 years old, who are operated for the diagnosis pectus excavatum by the Nuss-procedure in the participating centres.
Intervention: The intervention group will receive several music interventions, delivered by headphone, prior and during surgery, as well as post-operatively. The control group will only receive headphones during surgery but no music will be played.
Main study parameters/endpoints: The main study endpoint is self-reported pain-scores defined on the Visual Analogue Scale (VAS). Other endpoints are the amount of morphine used in the first three days postoperative as calculated by the Morphine Equivalent Dose Daily/ kilogram (MEDD/kg), levels of anxiety and distress, Quality of Life and physiological parameters such as heart rate, saturation and blood pressure.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The use of music as intervention has no known deleterious effects on patients. Safety precautions will be taken to limit the volume of the music on headphones during surgery. Patients in all study arms will receive standard perioperative care. Post-operative care and pain control will be performed according to standard protocols in the different centres of research. Burden includes the completion of several questionnaires. Measurements of vital signs will be collected from normal care data. No extra site visits will be necessary for participation in this study besides the regular check ups at the outpatient clinic. This research is performed in minors from 12 years and older as well as adults, as this operation is mainly done in the age of 12 to 16 years, however it is also performed in adults.

Doel van het onderzoek

Music interventions will reduce anxiety and pain in patients undergoing a nuss bar procedure due to pectus excavatum

Onderzoeksopzet

At outpatient clinic, during hospitalization until the third day of hospitalization, 3 months postoperative at the outpatient clinic

Onderzoeksproduct en/of interventie

Music interventions pre-, intra- and postoperatively

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

 Age 12 – 18 years
 Scheduled for primary PE repair according to the Nuss-procedure with either one or multiple bars
 Postoperatively, initial placement of a thoracic epidural or both thoracic epidural and patient-controlled analgesia system
 Good knowledge of the Dutch language, by both patients and parents

 Written informed consent. Additional written informed consent by parents or legal guardian is only necessary for children under the age of 16 years.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

 Hearing impairment
 Secondary PE surgery or other prior thoracic surgery
 Known severe mental or psychiatric disorder
 Known impaired communication with patient and parents as collected
 Presence of chronic pain syndrome: ongoing pain lasting longer than 3 months or ongoing pain lasting longer than the reasonably expected healing time for the involved tissues)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-06-2018
Aantal proefpersonen:	170
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	22-02-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6863
NTR-old	NTR7041
Ander register	METC EMC : 2016543

Resultaten