Music Under Surgery In Children

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON19989

Source
Nationaal Trial Register

Brief title
MUSIC

Health condition

music intervention, preoperative anxiety, postoperative pain, parental anxiety.

Sponsors and support

Primary sponsor: Sophia Kinderziekenhuis Rotterdam
Source(s) of monetary or material Support: Stichting Swart van Essen, WM de Hoop Stichting, Dokter Izak Wessel Stichting

Intervention

Outcome measures

Primary outcome

distress intensity assessed with the COMFORT behavior scale at t=1,t=2, t=4,t=5, t=6, t=7

Secondary outcome

salivary cortisol at t=1, t=3, t=4

heart rate at t=0, t=1, t=2, t=5, t=6, t=7

blood pressure at t=0, t=1, t=2, t=5, t=6, t=7

heart rate, blood pressure, saturation during anesthesia and surgery at t=3 and t=4

observed pain at t=1,t=2, t=4,t=5, t=6, t=7

use of medication at t=1 t/m t=7

parental anxiety at t=0, t=2

parental heart rate at t=0, t=2

parental anxiety and need for information at t=1

Study description

Background summary

This study will investigate the effects of a music intervention on distress, anxiety and pain in pediatric surgery. Surgical procedures are accompanied by high levels of distress and pain in the adult as well as the pediatric population. Studies in adult populations found that music interventions prior to and during surgery can alleviate anxiety and distress surrounding surgery and postoperative pain. In this study, we will investigate the hypothesis that music interventions prior to and during surgery will result in less anxiety and distress in infants undergoing surgical procedures.

The research will take place in children in the age of 0-3 years who will have surgery for inguinal hernia, undescended testicle or hypospadias.

This study will be performed as a single-blinded randomized controlled intervention study. Patients will be allocated to one of three study arms, resulting in two, one or no music interventions. Music interventions are administered by headphone. Subjects will listen to an appropriate music intervention, as reported in literature and recommended by music therapists.

The effect of the music intervention will be monitored during the first 24 hours after surgery. All patients will be recruited in The Netherlands.

Study objective

Surgical procedures are accompanied by high levels of distress and pain in the adult as well as the pediatric population. Music interventions have shown to reduce this anxiety and pain

in adult populations. In this study, we will investigate the hypothesis that music interventions prior to and during surgery will result in less anxiety, distress and pain in infants undergoing surgical procedures.

Study design

t=0 outpatient clinic

t=1 ward

t=2 holding area

t=3 start of surgery

t=4 end of surgery

t=5 30 minutes postoperatively

t=6 4 hours postoperatively

t=7 24 hours postoperatively

Intervention

Patient randomly allocated to one of three intervention groups:

1. music intervention prior to and during surgery

2. music intervention prior to surgery

3. control group, no music intervention, receives standard care.

Patients in group 1 and 2 receive music intervention by headphone for approximately 15 minutes prior to surgery, patients in group 3 receive standard care. During surgery, all patients receive headphones, but only patients in group 1 will have a music intervention.

Contacts

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Eligibility criteria

Inclusion criteria

-Age 0-3 years (inclusively 3 years), both male and female

-Scheduled for surgery for inguinal hernia (uni- or bilateral), undescended testicle (uni- or bilateral), hypospadias

-American Society of Anesthesiologists (ASA) physical status 1 and 2

-General anaesthesia with caudal block

-Parents good knowledge of the Dutch or English language

-Signed informed consent

Exclusion criteria

-Age ≥ 4 years

-Hearing impairments

-Emergency surgery

-Premedication with midazolam

-Impaired communication with parents

-Difficulties in speaking and reading Dutch or English in parents

-Missing informed consent

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-08-2015
Enrollment:	195
Type:	Actual

Ethics review

Positive opinion

Date:	26-08-2015
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	NL5293
NTR-old	NTR5402
Other	METC Erasmus MC Rotterdam : MEC 2015-264 NL53900.078.15

Study results