

# Music Under Surgery In Children

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Penile and scrotal disorders (excl infections and inflammations)
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON43650

### Source

ToetsingOnline

### Brief title

MUSIC

### Condition

- Penile and scrotal disorders (excl infections and inflammations)
- Skin and subcutaneous tissue therapeutic procedures

### Synonym

hypospadias or defect in opening of penis, inguinal hernia or groin hernia, orchidopexy or undescended testicle

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam

**Source(s) of monetary or material Support:** Stichting Swart van Essen;WM de Hoop stichting;Dokter Izak Wessel Stichting

## Intervention

**Keyword:** Music, Pediatrics, Postoperative Pain, Surgery

## Outcome measures

### Primary outcome

The main study outcome is distress intensity assessed with the Comfort-B scale.

Preoperative anxiety at induction and physiological parameters such as blood pressure are secondary outcome parameters to assess physiological stress. Also, the amount of postoperative pain and possible relation of distress in children regarding to distress in their parents are secondary parameters.

### Secondary outcome

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. Patients in all study arms will receive standard perioperative care. Burden includes the completion of several questionnaires and two measurements of heart rate by parents. Measurements of vital signs will be collected from normal care data. No extra site visits will be necessary for participation in this study. This research is performed in minors, as the additive value of this intervention in these age groups has not been sufficiently studied.

## Study description

### Background summary

This study will investigate the effects of a music intervention on distress, anxiety and pain in 0-to-3-year-old infants undergoing surgery. Studies in

adult patients found that music interventions prior to surgery can alleviate anxiety and distress surrounding surgery. Music interventions during surgery, either when the patient is awake or asleep, can also reduce physiological stress, anxiety 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.

## **Study objective**

The main objective of this study is to investigate whether a music intervention as complementary treatment is effective in reducing anxiety and distress around surgery. Secondary objectives are effects of music on pain, on preoperative anxiety, on physiological parameters such as blood pressure and on the amount of required analgesics. Possible relation of distress in children regarding to distress in their parents is investigated.

## **Study design**

This study will be performed as a randomized controlled intervention study.

## **Intervention**

Patients will be allocated to one of three study arms. The patients in the first study arm will receive both pre-operative and intraoperative music intervention; the patients in the second study arm will only receive preoperative music intervention; the patients in the third study arm will receive no intervention and serve as control group. All subjects will wear headphones during surgery. Subjects will listen to an appropriate music intervention consisting of string instruments, as reported in literature and recommended by music therapists.

## **Study burden and risks**

Subjects will be filmed for 5 or 6 times during 2 minutes, for afterwards evaluation of the Comfort-assessment and modified Yale preoperative anxiety scale by a trained observer. Subjects will also be filmed during the pre-operative music intervention. All films will be deleted at the end of the study. Burden is minimal. Parents of subjects will be asked for participation in 3 questionnaires, which will take 3-5 minutes for each questionnaire. Their heart rate will be measured twice.

There are no known deleterious effects of listening to music. Annually, many surgeries are performed in this patient population. This simple, non-pharmacological intervention might easily reduce anxiety and discomfort around surgeries in this patient population.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Children (2-11 years)

### Inclusion criteria

- Age 0-3 years (inclusively 3 years)
- 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:	Open (masking not used)

**Primary purpose:** Treatment

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	28-08-2015
Enrollment:	195
Type:	Actual

## Ethics review

Approved WMO	
Date:	31-07-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	
Date:	11-04-2016
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

No registrations found.

### In other registers

Register	ID
CCMO	NL53900.078.15