A study to evaluate the pain and anxiety reducing effects of music during gynecological outpatient procedures.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23130

Source
NTR

Brief title
GENTLE trial.

Health condition

Pain, anxiety, Patient satisfaction. Hysteroscopy, endometrial ablation with Novasure, colposcopy. Music.

Sponsors and support

Primary sponsor: Initiator
Source(s) of monetary or material Support: initiator/ selffunding

Intervention

Outcome measures

Primary outcome

Significant pain reduction using the Visual Analogue Scale(VAS).

Secondary outcome

Anxiety reduction using STAI
Heart rate
Patient satisfaction
Doctor satisfaction

Study description

Background summary

The aim of this study is to determine if patients who undergo an ambulatory hysteroscopy, colposcopy or Novasure endometrial ablation, experience less pain and/or anxiety with the addition of music to the procedure.
Country of recruitment: the Netherlands.

Study objective

There is some evidence that patients tend to experience less pain and anxiety while listening to music during an office procedure like colposcopy, hysteroscopy of endometrial ablation. The aim of this study is to prove a significant reduction of pain while listening to music.

Study design

Time points: 1.Just before consultation (questionnaire including State-Trait Anxiety Inventory list (STAI)and measurement of heart rate), 2. during procedure using Visual Analogue Scale at specific predefined moments. With colposcopy at the moment of biopsy or LEEP, with hysteroscopy at the moment of passage through internal os and with Novasure during ablation (VAS pain score and measurement of heart rate), 3.directly after the procedure (Short questionnaire including VAS pain score and STAI).

Intervention

The intervention group get to listen to music of choice during the office procedure. The control group doesn’t listen to music and these patients will be treated as in the normal daily practice.

Contacts

Public

[default]
The Netherlands
Scientific

[default]
The Netherlands

Eligibility criteria

Inclusion criteria

Dutch speaking females with the age of 18 or above, indication for office hysteroscopy, endometrial ablation or colposcopy, written informed consent.

Exclusion criteria

History of conization or Manchester Fothergill operation, blindness, severe hearing impairment/ deafness.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-09-2014
Enrollment:	202
Type:	Anticipated

Ethics review

Positive opinion

Date:	26-11-2014
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	NL4785
NTR-old	NTR4924
Other	METC Maxima Medisch Centrum : 2014-28

Study results