Virtual Reality ter pijnverlichting bij hysterosalpingografie

No registrations found.

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

Summary

ID

NL-OMON28038

Source
NTR

Brief title
VICTORY

Health condition

Infertility / tubal pathology

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

The primary endpoint is pain during the HSG. This measure consists of two components: the most severe pain (using a visual analogue scale 0-10) and the overall pain (using a visual analogue scale 0-10)

Secondary outcome

Secondary endpoints are:
- (Hypothetical) willingness to undergo another HSG if necessary
- Use of oral analgesics during the first 24 hours after the HSG
- ‘Immersiveness’ in the VR program
- Side effects of the VR program

Study description

Background summary

Aim: The aim of this study is to investigate whether the use of Virtual Reality can reduce pain during HSG.

Study Design: Single center randomized controlled trial

Study population: Women undergoing an HSG with oil-based contrast for insubfertility.

Intervention: Virtual Reality with the use of a ‘head mounted device’ (Sync VR Medical, Utrecht, The Netherlands) during the HSG. Participants will receive a demo of the VR device prior to the HSG and can choose between different relaxing and distracting modules. Questionnaires will be administered before and after the HSG.

Main study parameters: The primary endpoint is pain during the HSG. This measure consists of two components: the most severe pain (using a visual analogue scale 0-10) and the overall pain (using a visual analogue scale 0-10).
Secondary endpoints are:
- (Hypothetical) willingness to undergo another HSG if necessary
- Use of oral analgesics during the first 24 hours after the HSG
- ‘Immersiveness’ in the VR program
- Side effects of the VR program

Study objective

We expect that an HSG with use of Virtual Reality will decrease pain perception

Study design

Follow-up is 24 hours after HSG

Intervention

Virtual Reality with the use of a ‘head mounted device’ (Sync VR Medical, Utrecht, The Netherlands) during the HSG. Participants will receive a demo of the VR device prior to the HSG and can choose between different relaxing and distracting modules.

Contacts

Public
Amsterdam UMC
Kimmy Rosielle

020-4444567
Scientific
Amsterdam UMC
Kimmy Rosielle

020-4444567

Eligibility criteria

Inclusion criteria

Women who:
- Will undergo an HSG with oil-based contrast for infertility
- Have no history of cervical procedures
- Speak Dutch or English

Exclusion criteria

Women who:
- Are on chronic pain medication
- Use antidepressants or sedatives
- Underwent an HSG before
- Are unwilling or unable to give ‘informed consent’
- Are pregnant
- Have a malignancy

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):	19-01-2021
Enrollment:	134
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	16-01-2021
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	NL9203

Register	ID
Other	METc VUmc : 2020.0687

Study results