

Electronic continuous pain measurement versus Verbal Rating Scale in gynaecology

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		<input type="checkbox"/> Protocol
Registration date 30/01/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 23/01/2017	Condition category Urological and Genital Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Minimally invasive surgery is becoming more and more common in hospitals. These procedures are performed through tiny incisions instead of one large opening, and can greatly reduce the length of surgery and the recovery time. More and more gynaecological procedures (procedures on women's reproductive parts) are performed in an outpatient setting thanks to the development of these minimally invasive procedures, mostly performed without the need for sedation. During the procedure, patients' perception of pain plays a key role in how well they are able to tolerate the procedure. Pain perception is usually measured using pain scores, where participants are asked to rate their level of pain at certain timepoints, however this technique is not always accurate. Being able to effectively measure pain levels during the different parts of a procedure could therefore help better deliver pain relief which could make procedures more successful. The Continuous Pain Score Meter (CPSM) is a new electrical device which has been developed to continuously monitor pain levels throughout the operation. The aim of this study is to compare the effectiveness of this device at assessing pain, compared to standard techniques.

Who can participate?

Women aged between 18 and 80 who are scheduled to have a gynaecological procedure in an outpatient setting.

What does the study involve?

Before having their surgery, participants are asked to rate how anxious they are feeling. They then receive the surgery they have been scheduled for while they are awake. The women are given the CPSM meter and instructed about how to use it. They are then asked to express their pain throughout the procedure using the device so that their pain levels can be assessed continuously. After the surgery, they are asked to rate the average pain level they felt during the procedure using a standard verbal scale. Two years later, participants are telephoned to ask them to rate the pain felt in their surgery using a standard verbal scale from what they remember.

What are the possible benefits and risks of participating?

There are no direct benefits involved with participating. There is a risk that participants may experience discomfort whilst having their procedures performed.

Where is the study run from?

1. Onze Lieve Vrouwe Gasthuis (Netherlands)
2. VU University Medical Center (Netherlands)

When is the study starting and how long is it expected to run for?

June 2011 to January 2017

Who is funding the study?

VU University Medical Center (Netherlands)

Who is the main contact?

Miss Marjoleine Louwerse

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Study information

Scientific Title

Electronic continuous pain measurement versus Verbal Rating Scale in gynaecology: a prospective observational cohort study

Study objectives

The aim of this study is to:

1. Compare pain measurement between a new electronic device, the Continuous Pain Score Meter (CPSM) and the Verbal Rating Scale (VRS) during gynaecological procedures in an outpatient setting
2. Correlate these outcomes with baseline anxiety, with scored tolerability of the procedure and with pain perception 2 years after the procedure

Ethics approval required

Old ethics approval format

Ethics approval(s)

No ethical approval was deemed necessary for this non-WMO required study.

Study design

Prospective multi-centre observational cohort study

Primary study design

Observational

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Gynaecological procedures

Interventions

Before the procedure, patients have their anxiety score recorded. When the patient is positioned, she receives instructions on the use of the CPSM and as a part of this instruction the meter is tested once before the start of the procedure by giving the patient a mild pressure stimulus on her hand. Then, women are asked to express their pain by controlling the CPSM during the entire procedure. Immediately after the procedure, participants are asked to express the experienced average pain during the entire procedure, using the Verbal Rating Scale (VRS). Tolerability of the procedure is also reported at this point.

After a period of two years women are telephoned and asked to report the VRS and tolerability of the procedure again to determine what the effect is of recollection on pain perception.

Intervention Type

Device

Primary outcome(s)

Pain of outpatient gynecological procedure is measured using the Verbal Rating Scale (VRS 0-10) directly after a procedure versus pain measurement and using the Continuous Pain Score Meter (CPSM, CPSM-AUC, CPSM-PPS, CPSM-APS) during the procedure.

Key secondary outcome(s)

1. Recollection of pain perception is assessed using the Verbal Rating Scale (VRS 0-10) after two years
2. Anxiety is measured using a numerical rating scale (0-10) at baseline
3. Tolerability of the procedure is assessed post-surgery and after two years

Completion date

01/01/2017

Eligibility

Key inclusion criteria

1. Aged between 18-80 years
2. Scheduled for a hysteroscopy, colposcopy or ovum pick-up in an outpatient setting

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

80 years

Sex

Female

Key exclusion criteria

1. Inability to comprehend Dutch or English properly
2. For hysteroscopy: pregnancy or women in the luteal phase without the use of contraception, known cervical stenosis or malignancy, current Sexual Transmitted Disease (STD) or Pelvic Inflammatory Disease (PID) or contra-indications for the use of NSAIDs

Date of first enrolment

01/08/2011

Date of final enrolment

30/11/2011

Locations**Countries of recruitment**

Netherlands

Study participating centre**Onze Lieve Vrouwe Gasthuis (Location East)**

Oosterpark 9

Amsterdam

Netherlands

1091 AC

Study participating centre**VU University Medical Center**

De Boelelaan 1117

Amsterdam
Netherlands
1081 HV

Sponsor information

Organisation

VU University Medical Center

ROR

<https://ror.org/00q6h8f30>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

VU University Medical Center

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Marjoleine Louwerse (mail@marjoleinelouwerse.nl)

IPD sharing plan summary

Available on request