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Electronic continuous pain measurement versus Verbal Rating Scale in gynaecology

Submission date
19/01/2017

Recruitment status
No longer recruiting

Registration date
30/01/2017

Overall study status
Completed

Last Edited
23/01/2017

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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
mail@marjoleinelouwerse.nl

Contact information

Type(s)
Scientific

Contact name
Miss Marjoleine Louwerse

Contact details
VU University Medical Center
De Boelelaan 1117
Amsterdam
Netherlands
1081 HV
+31 20 444 4444
mail@marjoleinelouwerse.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
No participant information sheet available

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 measure

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.

Secondary outcome measures
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

Overall study start date
01/06/2011

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Female

Target number of participants
Number of patients included; Colposcopy: n=51, Ovum pick-up: n=27, Hysteroscopy: n=30

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

Sponsor details
De Boelelaan 1117
Amsterdam
Netherlands
1081 HV
+31 20 444 4444
j.huirne@vumc.nl

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
VU University Medical Center

Results and Publications

Publication and dissemination plan
Manuscript is ready for publication. Intending first submission BJOG end of January 2017.

Intention to publish date
31/12/2017

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