Patient education and postoperative pain.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20849

Source
Nationaal Trial Register

Health condition

postoperative pain, patient education, pain assessment.
postoperatieve pijn, patientenvoorlichting, pijnmeting.

Sponsors and support

Primary sponsor: University Medical Center Utrecht, The Netherlands
Source(s) of monetary or material Support: UMC Utrecht and Fonds NutsOhra

Intervention

Outcome measures

Primary outcome

The main study endpoint is the patient's postoperative pain score on the NRS and the expressed need for (more) opioids by the patient.
Pain will be measured in each patient on the ward on the day after surgery by trained research nurses who are not involved in the postoperative care of that patient and are not aware of the study group in which the patient is included. The patient will be asked to score the enduring pain on an 11 point scale, where 0 indicates no pain and 10 indicates the worst imaginable pain. After the assessment of pain the patients will be asked if they want to have

(more) morphine.

Secondary outcome

The secondary endpoint is knowledge, attitude, anxiety and self-efficacy of the patient. Furthermore, the amount of information a patient needs.

Preoperative anxiety has been seen to influence patients to experience more pain after surgery. Furthermore, preoperative information is considered to be an important tool in helping patients to reduce the anxiety associated with surgery and pain.

Self-efficacy is defined as a belief that one can effectively perform a given behaviour and the behaviour will result in desired outcomes. Self-efficacy concerns control over specific behaviours necessary in handling pain and pain relief.

Anxiety (Fear of surgery questionnaire) and attitude (Patient Barriers questionnaire) will be measured by standard questionnaires. Knowledge and self-efficacy questions will be based on literature and expert opinion.

Undergoing surgery is a threatening event for many patients. It is important that patients are adequately prepared prior to surgery. Miller's monitoring-blunting model concerns the processing of health information while some patients want more information (monitors) and some less (blunters). Therefore, monitoring and blunting coping styles were assessed by means of the Threatening Medical Situations Inventory (TMSI).

The tertiary endpoint is the patient's pain score on a Verbal Rating Scale (VRS). The VRS contains five expressions:

1. No pain;

2. Little pain;

3. Painful but bearable;

4. Considerable pain;

5. Terrible pain.

The first three categories together (no pain, little pain and painful but bearable) are considered bearable and the last two categories together (considerable pain and terrible pain) are deemed unbearable.

Study description

Background summary

Rationale:

A patient’s pain score on the Numeric Rating Scale (NRS) is a leading indicator in postoperative pain treatment. Previous studies show different interpretations of the NRS score between patients and professionals. A risk of under- or overtreatment might arise when health care providers rigidly follow guidelines that prescribe strong analgesics. Patients need to be better educated about the NRS score and pain treatment to prevent under- or overtreatment with opioids.

Objective:

Does an educational film seen before surgery change the postoperative expressed need for opioids by the patient? Does an educational film improve patients’ knowledge, attitude and self-efficacy and decrease anxiety towards postoperative pain and pain management?

Study design:

The study is a Randomized Controlled Trial.

Study population:

Adult patients scheduled for elective surgery and visiting the Outpatient Preanaesthesia Evaluation Clinic in UMC Utrecht.

Intervention:

The intervention of interest is an educational film on postoperative pain, pain assessment (NRS) and pain medication; the film lasts five minutes. The control group will see a film about the infotainment system of the hospital; this film lasts three minutes.

Study objective

An educational film seen before surgery change the postoperative expressed need for opioids by the patient (i.e., increase when postoperative patients report NRS > 4 and decrease when patients report NRS ≤ 4).

Study design

1. After watching the film the patient is asked to fill in a questionnaire containing questions whether the patient understood the message of the film and the TMSI;

2. Two weeks before surgery a questionnaire will be send to the patient by mail and with an invitation to fill in and send the questionnaire back with the return envelop. Demographic data (age, gender, educational level and preoperative pain) will be collected;

3. The day after surgery, the pain scores (NRS and VRS) and the expressed need for (more) opioids will be collected.

Intervention

The intervention of interest is an educational film on postoperative pain, pain assessment (NRS) and pain medication. The film lasts four minutes. The control group will see a film about the infotainment system of the hospital. This film lasts three minutes.

Contacts

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Eligibility criteria

Inclusion criteria

All elective surgery patients of 18 years and older visiting the Outpatient Preanaesthesia Evaluation Clinic in UMC Utrecht.

Exclusion criteria

1. Patients younger than 18 years;

2. Patients for ambulatory surgery;

3. Patients who do not adequately understand Dutch;

4. Patients with mental impairment.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2011
Enrollment:	350
Type:	Actual

Ethics review

Positive opinion

Date:	10-10-2011
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	NL2948
NTR-old	NTR3095
Other	UMC Utrecht : 11-280/E
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A