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Postoperative pain: knowledge and beliefs of patients and nurses

Submission date	Recruitment status	[ ] Prospectively registered
29/09/2016	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
04/10/2016	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/10/2016	Signs and Symptoms	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Many patients experience pain after surgery (postoperative pain). The day after surgery, patients who have undergone different types of surgery often high report high levels of pain, indicated by scores over 4 on the Numeric Rating Scale (NRS) that is used to assess pain. A patient's pain score on the NRS indicates their need for pain treatment. Previous research has shown that healthcare professionals' interpretations of pain are not in line with the patients' actual perceptions of pain. Most patients consider pain with an NRS score of 4–6 as bearable, while acute pain nurses consider pain with an NRS score over 4 as unbearable. In clinical practice, many patients who report NRS scores over 4 refuse analgesics (painkillers) that are offered according to the guidelines for pain management. It is not known why patients give high NRS scores but refuse analgesics, especially opioids. It is important that patients accept opioids when they are in pain, not only for their comfort, but also to prevent complications such as a pneumonia (chest infection) and thrombosis (blood clots). Specific information given before surgery about pain and pain treatment may help patients to achieve better pain relief. The aim of this study is to measure the influence of written information on patients' knowledge and beliefs about pain and pain management after surgery.

Who can participate?
Adult patients scheduled for elective surgery (i.e., does not involve a medical emergency) at a university hospital

What does the study involve?
Before undergoing surgery the participants are randomly allocated either to receive information about postoperative pain and its potential complications or to not receive the information. After filling in questionnaires assessing their knowledge and beliefs about postoperative pain management, participants had the usual care preoperative consultation including general information about postoperative pain management.

What are the possible benefits and risks of participating?
Participants may be better informed before their operation and accept more pain treatment after the operation. There are no risks involved in this study.

Where is the study run from?
University Medical Center (Netherlands)

When is the study starting and how long is it expected to run for?
April to July 2013

Who is funding the study?
University Medical Center (Netherlands)

Who is the main contact?
Dr J.F.M. van Dijk
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
12/567

Study information

Scientific Title
Postoperative pain: knowledge and beliefs of patients and nurses - a randomised controlled trial

Study objectives
Reading information about postoperative pain complications increases patients' knowledge and belief relative to patients who had no extra information.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Ethics Committee of the University Medical Center Utrecht, 27/11/2012, ref: 12-567

Primary study design

Interventional

Study design
Single-centre randomised controlled trial

Study type(s)
Other

Health condition(s) or problem(s) studied
Postoperative pain

Interventions
A researcher explained the purpose of the study to all eligible patients at the Outpatient Preoperative Evaluation (OPE) clinic while they were waiting for their preoperative consultation. Thereafter, they were asked to participate. Questionnaires with or without information about the postoperative complications of pain were inserted in sealed opaque envelopes, shuffled, and sequentially numbered. The envelopes were only opened when patients agreed to participate.

For the patients in the intervention group, the questionnaires with information started with a short (87-word) paragraph: “It is possible that you will have pain after surgery. Usually, we can treat this pain adequately. If you have severe pain, we can administer a strong analgesic, such as morphine. If severe pain is not adequately treated, it can have negative health consequences. Pain is unpleasant and can cause complications. Severe pain can cause pneumonia if it prevents you from coughing after surgery, and thrombosis can occur if it prevents you from moving normally. Therefore, good pain management can prevent complications.” This text was derived in a meeting with experts on pain management and patient education.

Patients in the control group received the same questionnaire but without information, simply starting with the first question.

The researcher asked them to read the text first if they had not done so before beginning to answer the questions. To ensure this procedure the researcher observed the respondent during the reading and answering. The questionnaires were read aloud for patients with impaired eyesight. After filling in the questionnaires, patients had usual care preoperative consultation including general information about postoperative pain management.

There were no valid baseline assumptions possible regarding the difference in knowledge and beliefs between the two groups therefore formal power calculation was not feasible. Data collection of the study was planned for a period of three months, including as many patients as possible in this period. There is no follow-up.

Intervention Type
Other

Primary outcome(s)
Knowledge and beliefs about postoperative pain management, measured using the Pain Knowledge Questionnaire and the beliefs subscale of the Barriers Questionnaire at the single study visit

Key secondary outcome(s)

N/A

Completion date
09/07/2013

Eligibility

Key inclusion criteria
Adult patients scheduled for elective surgery at a university hospital

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Patients unable to understand Dutch

Date of first enrolment
02/04/2013

Date of final enrolment
09/07/2013

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Center
Heidelberglaan 100
Netherlands
3584 CX

Sponsor information

Organisation

Astellas Pharma BV

ROR
https://ror.org/04kyfd050

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Universitair Medisch Centrum Utrecht

Alternative Name(s)
UMC Utrecht, University Medical Center Utrecht, UMCU, UMC

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study are available from Jacqueline van Dijk (j.f.m.vandijk@umcutrecht.nl) on reasonable request

IPD sharing plan summary
Available on request