ISRCTN53835337 https://doi.org/10.1186/ISRCTN53835337

The impact of individual conversation and information intervention on preoperative anxiety and postoperative pain

Submission date
20/12/2013

Recruitment status
No longer recruiting

Registration date
24/01/2014

Overall study status
Completed

Last Edited
29/05/2020

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Hysterectomy is the surgical removal of the uterus and is the most common major gynaecological surgery worldwide. In Denmark about 5,000 hysterectomies are performed annually. There are many reasons for hysterectomy. Regardless of the condition hysterectomy is usually performed due to a benign disorder such as irregular bleeding, benign growths, pain and bulging of the uterus. The surgery is performed to improve women's quality of life and can be performed through the abdominal cavity as a keyhole surgery or through the vagina. Many patients experience anxiety before surgery. This has been shown to be mainly due to their fear of losing fertility, femininity and attractiveness. Thorough information about the process before, during and after hospitalization make the patient more comfortable, which leads to less anxiety. Studies have shown that the level of anxiety before an operation is closely related to the patient's experience of surgical pain i.e. the lower the level of anxiety is before the surgery, the lower the level of surgical pain is after the surgery. This study aims to find the effectiveness of an individual conversation and information on anxiety before surgery and pain afterwards.

Who can participate?
Participant must be age 18 or over, and must have been referred to hysterectomy on a benign indication.

What does the study involve?
Participants will be randomly allocated to the intervention or the control group. The participants in the intervention group will be invited to have an individual conversation before the surgery and will be given information. The conversation and information will be based on a structured form where the current course of hospitalization is reviewed and patient concerns/expectations are discussed. The control group will be offered information as usual. Both groups will complete a diary during hospitalization and answer a questionnaire at 4 weeks.

What are the possible benefits and/or risk of participating?
The possible benefits of participating in this study include a lower level of anxiety and less postoperative pain. For some it may be pleasant to experience a professionally planned

conversation. Participation in this study is not believed to have any risks or side effects. Extra time spent at the consultation and completing the diary and questionnaire are considered to be of minor inconvenience.

Where is the study run from?
The study is run from the Research and Gynaecological units at Horsens Regional Hospital, Denmark.

When is the study starting and how long is it expected to run for?
The study started in November 2013 and is expected to run until February 2015.

Who is funding the study?
The study is funded by the Horsens Regional Hospital (Denmark) and The Family Hede Nielse Foundation (Denmark).

Who is the main contact?
Mrs Hrønn Thorn
johtho@rm.dk

Contact information

Type(s)
Scientific

Contact name
Mrs Hrønn Thorn

Contact details
Kvindeafdelingen
Sundvej 30
Horsens
Denmark
8700
+45 7842 6443
johtho@rm.dk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
39621

Study information

Scientific Title

Individual conversation and information as anxiety prevention: preoperative anxiety and postoperative pain, among women with abdominal hysterectomy of benign indication

Study objectives
Women who are about to get their uterus removed by a surgical procedure have more anxiety than other surgical patients and furthermore it is known that there is an association between preoperative anxiety and postoperative pain. Our hypothesis is that predictability through comprehensive information can reduce the preoperative anxiety level and thereby reduce the level of postoperative pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The scientific committees of Central Denmark Region, 17/10/2013

Study design
Single-center randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient infrmation sheet

Health condition(s) or problem(s) studied
Hysterectomy of benign indication

Interventions
Randomization will be stratified in blocks of 8 in order to ensure an equal distribution over time. Patients will be randomized to two groups:
1. Intervention: a preoperative individual conversation and information. The conversation and information will be based on a structured form where the current course of hospitalization is reviewed and patient concerns/expectations are discussed.
2. Control: information as usual

All participants will complete a diary during hospitalization and answer a questionnaire at 4 weeks postoperatively.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Pain is measured on a Visual Analog Scale (VAS). Measurements will be performed twice: at baseline and at 4 weeks.

Secondary outcome measures
1. Anxiety is measured on State Trait Anxiety Inventory (STAI)
2. Nausea, measured on a VAS

Measurements will be performed twice: at baseline and at 4 weeks. Incidence of nausea and vomiting, diet and fluid intake, activity, postoperative hospital stay.

Overall study start date
01/11/2013

Completion date
31/01/2015

Eligibility

Key inclusion criteria
1. Age 18 or over
2. Referred to abdominal hysterectomy
3. Read and understand Danish
4. Informed written consent and authorization given

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
80

Key exclusion criteria
1. Anxiety and other mental disorders
2. Daily use of anxiolytic
3. Daily use of opioids

4. Allergic to opioids
5. Chronic pain
6. Body Mass Index (BMI) above 35

Date of first enrolment
01/11/2013

Date of final enrolment
31/01/2015

Locations

Countries of recruitment
Denmark

Study participating centre
Kvindeafdelingen
Horsens
Denmark
8700

Sponsor information

Organisation
Horsens Regional Hospital (Denmark)

Sponsor details
c/o Lisbeth Uhrenfeldt
The Research Unit
Sundvej 30
Horsens
Denmark
8700
+45 7842 6101
johtho@rm.dk

Sponsor type
Government

ROR
https://ror.org/021dmtc66

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The Horsens Regional Hospital (Denmark)

Funder Name
The Family Hede Nielse Foundation (Denmark)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	27/09/2019	29/05/2020	Yes	No