

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

Submission date 20/12/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 24/01/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 29/05/2020	Condition category Surgery	<input type="checkbox"/> 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?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

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)

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

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