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The effect of acupressure of PC6 on postoperative nausea and vomiting (PONV) after hysterectomy

Submission date
20/12/2013

Recruitment status
No longer recruiting

Registration date
24/01/2014

Overall study status
Completed

Last Edited
10/05/2021

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 women who have their uterus removed by surgical procedure experience nausea and/or vomiting after surgery [postoperative nausea and vomiting (PONV)]. The reason why women who undergo gynaecological surgery have more PONV than those undergoing other kinds of operations is yet not fully understood. However, it is clear that many things come into play, and that efforts to prevent and treat PONV are to be deployed from multiple sides. This study aims to find out the effectiveness of stimulating the acupressure point PC6 on the patients experience of PONV on the first day after the operation.

Who can participate?
Participants must be aged 18 or over and have been referred to have a laparoscopic or vaginal 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 get a Sea-Band bracelet on each arm. The bracelets will be placed on the arms about one hour before surgery and will be removed 24 hours after surgery. The bracelets will be placed so they stimulate the acupuncture point PC6. The control group will receive the usual treatment for PONV. Both groups will complete a diary during hospitalization.

What are the possible benefits and risks of participating?
The possible benefits of participating in this study are a lower intensity of nausea and vomiting. Participation in this study is not believed to have any risks. The Sea-Band may cause minor discomfort, such as itching, minor swelling or pain. The Sea-Band can be removed from the arms

for half an hour should this occur. Extra time spent at the consultation and completing the diary is considered to be of minor inconvenience.

Where is the study run from?
The study is run from the Research and Gynecological 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 Sea-Band Denmark (Denmark).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
39487

Study information

Scientific Title

Peroperative acupressure: Effectiveness on postoperative nausea and vomiting - a randomized clinical trial among women with hysterectomy of benign indication

Study objectives
Women who have had their uterus removed by a surgical procedure experience more postoperative nausea and vomiting than other surgical patients. It is well-known that stimulation of PC 6 can have a positive effect on PONV. There are studies indicating that especially gynecological patients experience a reduction in PONV. We propose to carry out a fully randomized clinical trial exploring the benefits of stimulating PC6 with Sea-Band, from about one hour before the surgical procedure and the next 24 hours.

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)
Treatment

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

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

Interventions
Patients are randomized to two groups:
1. Intervention group: in addition to the usual nausea treatment, women get a Sea-Band placed on each arm, so that PC6 is stimulated. The Sea-Band bracelets are placed by nurses who have completed the course "Acupuncture treatment of hyper emesis and postoperative nausea and vomiting". The Sea-Bands are maintained for 24 hours postoperatively. In case of discomfort, the Sea-Band may be removed for half an hour, and placed back on the arms by a nurse. The number and time will be registered in the diary by the participant.
2. Control group: usual treatment

Intervention Type

Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Nausea is measured on a Visual Analog Scale (VAS). Measurements will be performed three times at baseline, i.e. 2 and 6 hours postoperatively and at 10 am on the first postoperative day

Secondary outcome measures
1. Occurrence of vomiting (measured at baseline, questionnaire)
2. Quantity of required antiemetic (measured at baseline, patient record)
3. Time to first dose of required antiemetic (measured at baseline, patient record)
4. Diet and fluid intake (measured at baseline, questionnaire)
5. Pain score measured on a VAS (measurement will be performed at 2 and 6 hours postoperatively and at 10 am on the first postoperative day, questionnaire)
6. Quantity of required analgesics (measured at baseline, patient record)
7. Time to first required analgesics (measured at baseline, patient record)
8. Time to first mobilization (measured at baseline, questionnaire)
9. Postoperative hospital stay (measured at baseline, questionnaire)

Overall study start date
01/11/2013

Completion date
31/01/2015

Eligibility

Key inclusion criteria
1. Aged 18 or over
2. Referred to laparoscopic or vaginal 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
Target number: 70

Total final enrolment
72

Key exclusion criteria
1. Carpal tunnel syndrome
2. Diabetes
3. Nausea and vomiting preoperatively
4. Lymph edema
5. Skin diseases or wounds on the wrists
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)

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Sponsor type
Government

ROR
https://ror.org/021dmtc66

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Horsens Regional Hospital (Denmark)

Funder Name
Sea-Band Denmark (Denmark) - provides us with free bands on request

Results and Publications

Publication and dissemination plan

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?
Abstract results			29/05/2020	No	No