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Role of analgesia given in the peritoneum and through the site of wound before the end of operation in patients undergoing removal of undescended uterus through the vaginal route

Submission date
23/02/2017

Recruitment status
No longer recruiting

Registration date
07/03/2017

Overall study status
Completed

Last Edited
07/03/2017

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
A hysterectomy is a surgical procedure to remove the womb (uterus). This can be done in a number of ways, including through a cut in the top of the vagina (vaginal hysterectomy), through a cut in the lower tummy (abdominal hysterectomy) or through several small cuts in the tummy (laparoscopic hysterectomy). There are many reasons for undergoing a hysterectomy, including cancer and non-cancerous conditions of the female reproductive system. Following a hysterectomy, women tend to experience high levels of pain, and many require strong pain killers after the procedure. Ropivacaine is a local anaesthetic drug (injectable numbing medication) which works by blocking pain signals. The aim of this study is to find out whether injections of ropivacaine during surgery can help provide effective pain relief after surgery.

Who can participate?
Women aged between 45 and 70 who are having a vaginal hysterectomy.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group are given injections of ropivacaine at the site of the wound and in the peritoneum (space in the body that holds the organs in the abdomen) and those in the second group are given infections of a fluid in the same places that offers no pain relief (salt water) before the end of their surgery. Participants in both groups are then regularly asked to rate their pain levels up to 24 hours after surgery. In addition, the pain killers they receive and length of hospital stay is recorded.

What are the possible benefits and risks of participating?
There is a chance that the participants who receive the ropivacaine will benefit from lower pain levels after surgery. There are no notable risks of participating.

Where is the study run from?
Benha University Hospital (Egypt)

When is the study starting and how long is it expected to run for?
November 2013 to April 2016

Who is funding the study?
Benha University (Egypt)

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
563476

Study information

Scientific Title
Role of ropivacaine postincisional infiltration with intraperitoneal instillation analgesia in postoperative pain relief in patients undergoing non descent vaginal hysterectomy: Randomized controlled trial

Study objectives
The aim of this study is to establish whether ropivacaine postincisional infiltration with intraperitoneal instillation analgesia is effective in providing postoperative pain relief in patients undergoing non-descent vaginal hysterectomy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Internal Ethical Committee of Department of Obstetrics and Gynecology, 10/12/2013, ref: 344561

Study design
Double-blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Non descent vaginal hysterectomy

Interventions
Participants are randomised to one of two groups in a 1:1 ratio using computer generated block randomisation.

Intervention group: Participants are given ropivacaine at a total dose of 50 ml, 30 ml of which is injected locally and 20 ml into the peritoneum before the end of operation as pre-emptive analgesia.

Control group: Participants are given a fluid injection of saline at total of 50 ml, 30 ml of which is injected locally and 20 ml into the peritoneum before the end of operation.

Participants in both groups are assessed for side-effects and pain levels 0.5, 1, 2, 4, 8, 12 and 24 hours post-operatively.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Ropivacaine

Primary outcome measure
Pain is measured using the visual analogue score at 0.5, 1, 2, 4, 8, 12 and 24 hours post-operatively.

Secondary outcome measures
1. Time in hours to get out of bed after operation is measured by nurse responsible for the patient at 8 and 12 hours post-operatively
2. Hospital stay in days is measured by nurse at time of discharge of the patient
3. Total Narcotic dose (Nalbuphine) is measured by nurse at 1 and 24 hours post-operatively
4. Total parentral NSAID (diclofenac sodium) used in the first 24 hours after surgery is measured by nurse at 24 hours post-operatively
5. Number and proportion of patients with nausea and vomiting in the first 24 hours is measured by nurse at 24 hours post-operatively
6. Time spent in the post-anethesia care unit is measured by nurse at time of discharge from the post-anethesia care unit

Overall study start date
01/11/2013

Completion date
15/04/2016

Eligibility

Key inclusion criteria
1. Female
2. 45 to 70 years old
3. Scheduled for NDVH for benign indications without need for oophorectomy or vaginal reconstructive surgery

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Minimum of 42

Key exclusion criteria
1. Patient weight less than 50 kg
2. Allergy to amide local anathetic
3. Dementia or mental retardation to a degree which would interfere with data collection
4. Contraindication to non descent vaginal hysterectomy

Date of first enrolment

20/01/2014

Date of final enrolment
10/01/2016

Locations

Countries of recruitment
Egypt

Study participating centre
Benha University Hospital
Fareed Nada Street
Benha
Egypt
13511

Sponsor information

Organisation
Benha University

Sponsor details
Department of Obstetrics and Gynecology
Benha University Hospital
El-Shaheed Farid Nada, Qism Banha
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Sponsor type
University/education

ROR
https://ror.org/03tn5ee41

Funder(s)

Funder type
University/education

Funder Name
Benha University

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date