

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/03/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 07/03/2017	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 injections 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?
Dr Eman Omran
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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)

Study design

Double-blind randomised controlled trial

Primary study design

Interventional

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

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 parenteral 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-anesthesia care unit is measured by nurse at time of discharge from the post-anesthesia care unit

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Patient weight less than 50 kg
2. Allergy to amide local anesthetic
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

ROR
<https://ror.org/03tn5ee41>

Funder(s)

Funder type
University/education

Funder Name
Benha University

Results and Publications

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes