

# 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

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<b>Registration date</b> 07/03/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 07/03/2017	<b>Condition category</b> 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

**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 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

**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 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

**Sponsor details**

Department of Obstetrics and Gynecology

Benha University Hospital

El-Shaheed Farid Nada, Qism Banha

Al Qalyubia Governorate

Benha

Egypt

13511

**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