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How bowel preparation and deep neuromuscular blockade may affect field visualization and postoperative pain in patients undergoing gynecological laparoscopic surgery

Submission date
22/08/2017

Recruitment status
No longer recruiting

Registration date
30/08/2017

Overall study status
Completed

Last Edited
10/02/2021

Condition category
Surgery

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Laparoscopy (keyhole surgery) has achieved remarkable progress during the last three decades in the field of gynecologic surgery. The advantages of laparoscopy are shorter operative time, small wounds, faster recovery and less days in the hospital for the patient after the operation. Laxatives or a special diet before the operation (bowel preparation) is widely used in gynecologic surgery, with the aim of reducing complications and improving the viewing and handling conditions when the surgeon is working. This routine practice, however, is not based on scientific research results and patient risks and discomfort must be considered. On the other hand, muscle relaxation is a common anesthesia method that gives the surgeon a good operating field. Usually the anesthesiologists use moderate relaxation but recently advances in new drugs and instruments allow them to maintain deep muscle relaxation during the procedure. The benefit of maintaining deep neuromuscular blockade to improve surgical conditions has seldom been investigated. The aim of this study is to investigate the effect of different bowel preparation methods and deep neuromuscular blockade in operative field visualization and pain after surgery.

Who can participate?
Women aged over 18 undergoing a gynecological laparoscopic operation for a benign (non-cancer) pathology

What does the study involve?
Participants are randomly allocated to one of six groups: three groups using different bowel preparations (mechanical bowel preparation with PEG, 3 days of low residue diet and no preparation), which are randomly allocated further to use either deep neuromuscular blockade or usual moderate neuromuscular blockade during the laparoscopic operation. Surgical field quality is measured during the surgery and pain is measured 12 hours after the operation.

What are the possible benefits and risks of participating?
The possible benefit is improvement of the operating field with the use of bowel mechanical preparation and deep muscle relaxation, helping the surgeon. Deep blockade may also reduce pain after the surgery. If no benefit is found for mechanical bowel preparation this practice may be stopped, reducing patient discomfort from it.

Where is the study run from?
University of Athens, Alexandra Hospital (Greece)

When is the study starting and how long is it expected to run for?
September 2017 to September 2019

Who is funding the study?
University of Athens, Alexandra Hospital (Greece)

Who is the main contact?
Dr Nikolaos Kathopoulis

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Surgical and patient outcomes using bowel preparation and deep neuromuscular blockade before laparoscopic gynecologic surgery: a randomized controlled trial

Study objectives
Bowel preparation and deep neuromuscular blockade may affect operating field visualisation and postoperative pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Scientific Board of Alexandra Hospital, 12/02/2015, ref: 74/12-02-2015

Study design
Single-centre open-label prospective single blind randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Bowel preparation and deep neuromuscular blockade in gynecological laparosocopic operations

Interventions
150 participants will be randomised to six groups prior to laparoscopic surgery using a six-subject computer generated blocked randomisation scheme. A third party research assistant not involved in patient recruitment or data collection will give a written preoperative dietary instruction sheet according to the allocated group of each patient. The surgeons will not be aware of the group that each patient is allocated to.

Group A1: Patients with no preoperative bowel preparation only liquid diet for 24 hours prior to laparoscopy and fasting for 8 hours prior to the operation. The usual moderate neuromuscular blockade was applied during all the duration of laparoscopy, from the time that the patient was anesthetized until the anesthesia has finished.

Group B1: Mechanical bowel preparation with 2 sachets of oral laxative (59g/sach of Polyethylene Glycol, 0,7425g/sach of Potassium chloride, 1,465g/sach of Sodium chloride, 1,685g /sach of Sodium bicarbonate) diluted in 1,5 litter of water and ingested 24 hours prior to laparoscopy. The usual moderate neuromuscular blockade was applied during all the duration of laparoscopy, from the time that the patient was anesthetized until the anesthesia has finished.

Group C1: Patients were on a minimal residue diet for 3 days prior to laparoscopy and fasting for the last 8 hours prior to the operation. The usual moderate neuromuscular blockade was applied during all the duration of laparoscopy, from the time that the patient was anesthetized until the anesthesia has finished..

Group A2: Patients with no preoperative bowel preparation only liquid diet for 24 hours prior to laparoscopy and fasting for 8 hours prior to the operation. Deep neuromuscular blockade was applied as a muscle relaxation method during all the duration of laparoscopy, from the time that the patient was anesthetized until the anesthesia has finished.

Group B2: Mechanical bowel preparation with 2 sachets of oral laxative (59g/sach of Polyethylene Glycol, 0,7425g/sach of Potassium chloride, 1,465g/sach of Sodium chloride, 1,685g /sach of Sodium bicarbonate) diluted in 1,5 litter of water and ingested 24 hours prior to the operation. Deep neuromuscular blockade was applied as a muscle relaxation method during all the duration of laparoscopy, from the time that the patient was anesthetized until the anesthesia has finished.

Group C2: Patients were on a minimal residue diet for 3 days prior to laparoscopy and fasting for the last 8 hours prior to the operation. Deep neuromuscular blockade was applied as a muscle relaxation method during all the duration of laparoscopy, from the time that the patient was anesthetized until the anesthesia has finished.

The bowel preparation methods will be applied from 3 days before the scheduled laparoscopic operation to 8 hours prior to that depending on the method used. Deep or moderate neuromuscular blockade is applied to the patient with the anesthesia during the laparoscopy.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Surgical field quality, measured with a 4-point VAS (0 very poor, 1 poor, 2 good, 3 very good) 15 minutes after the entrance of the central trocar
2. Postoperative pain, measured with a 5-point VAS (0 no pain, 4 severe pain) 12 hours after the operation completion

Key secondary outcome(s))
1. Symptoms measured with a 5-point VAS from the time the bowel preparation is applied until just before the patient's transportation from the room to the operation table:
1.1. Insomnia
1.2. Tiredness
1.3. Bloating
1.4. Abdominal cramps or pain
1.5. Nausea
1.6. Vomiting
1.7. Anal irritation
1.8. Weakness
1.9. Chest pain
1.10. Hanger pain
1.11. Thirst
2. Patient compliance with the completion of the bowel preparation, measured with questionnaire just before the patient's transportation from the room to the operation table
3. Patient opinion of the method of bowel preparation used, measured with questionnaire just before the patient's transportation from the room to the operation table
4. Ease of completion of the preparation, measured with questionnaire just before the patient's transportation from the room to the operation table
5. Postoperative symptoms and bowel function
5.1. Bloating, measured with a 5-point VAS 24 hours after the operation completion
5.2. Nausea, measured with a 5-point VAS 24 hours after the operation completion
5.3. Time of first gas passing after the operation, assessed by interview on the 3rd postoperative day
5.4. Time of first stool passing after the operation, assessed by interview on the 3rd postoperative day
6. Hospital stay (the number of postoperative days the patient stayed in the hospital)
7. Intraoperative complications during the length of the laparoscopic operation
7.1. Subcutaneous emphysema from the time the patient was anesthetized until recovered from the anesthesia
8. Postoperative complications, recorded with an interview with the patient 1 month after the operation
9. Hematocrit changes, measured from 24 hours before the operation and the 2nd postoperative day

Completion date
01/09/2019

Eligibility

Key inclusion criteria
1. Female patients
2. Aged over 18 years old
3. Patients with indication of laparoscopic gynaecological operation
4. Patients that may communicate sufficiently with the researcher
5. Patients that have signed an informed consent for their participation on the present study
6. Patients ASA class I-II
7. Patients with known allergy to Polyethylene Glycol (PEG)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
144

Key exclusion criteria
1. Age under 18 years old
2. Male patients
3. Patients with known gynecological cancer
4. Patients with irritable bowel syndrome
5. Patients with hepatic of renal failure
6. Laparoscopy converted to laparotomy
7. Patients ASA class III-VI

Date of first enrolment
01/09/2017

Date of final enrolment
01/04/2019

Locations

Countries of recruitment
Greece

Study participating centre
University of Athens
Alexandra Hospital
1st Department of Obstetrics and Gynaecology
Greece
11528

Sponsor information

Organisation
University of Athens

ROR
https://ror.org/03xawq568

Funder(s)

Funder type
University/education

Funder Name
National and Kapodistrian University of Athens

Alternative Name(s)
University of Athens

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Greece

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Nikolaos Kathopoulis. Individual participant data that underline the results after deidentification will be available beginning 9 months and ending 36 months following

publication. Data will be available to researchers who provide a methodologically sound proposal for data meta-analysis after communication with the investigator in charge. Other documents such as protocol, informed consent form and statistical analysis will be available.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2021	10/02/2021	Yes	No