ISRCTN87898051 https://doi.org/10.1186/ISRCTN87898051

Can postoperative pain be reduced by adding saline to the abdominal space following keyhole surgery?

Submission date
24/06/2019

Recruitment status
No longer recruiting

Registration date
26/06/2019

Overall study status
Completed

Last Edited
19/07/2023

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Pain after laparoscopic surgery or 'key-hole' surgery is common. Although it is less severe than conventional 'open' surgery, patients do experience pain over the shoulder and upper abdominal region (which is not related to the skin incision site) particularly after 24 hours of surgery. Painkillers do not seem to be effective in eliminating this pain.
Intraperitoneal normal saline infusion (infusing salt water in the abdomen) has been shown to be effective in reducing pain after laparoscopic surgery; however there is only one study done previously. The purpose of this study is to evaluate the effectiveness of the proposed treatment (intraperitoneal normal saline infusion) in reducing pain after laparoscopic surgery.

Who can participate?
Women aged 18 years and above scheduled for laparoscopic surgery for a benign gynaecological condition.

What does the study involve?
Participants will undergo surgery as usual however, half of the participants will receive the saline infusion following the procedure and half will receive the normal after-care. Participants will be asked to fill in a questionnaire and asked to rate their pain after surgery.

What are the possible benefits and risks of participating?
There may or may not be any benefits. Information obtained from this study will help improve the treatment or management of other patients with the same disease or condition in the future. During the study period, participants may experience nausea, vomiting, bloatedness, and abdominal discomfort post-operation, which are commonly experienced by most patients after surgery. Adequate painkiller and anti-vomiting medication will be given as per standard post-operative plan.

Where is the study run from?
University Malaya Medical Centre, Malaysia

When is the study starting and how long is it expected to run for?
July 2019 to December 2019

Who is funding the study?
investigator funded

Who is the main contact?
1. Prof. Aizura Syafinaz Ahmad Adlan,
aizuraadlan@gmail.com
2. Dr Hairel Mohd Tarmidzi,
hairel@gmail.com

Contact information

Type(s)
Scientific

Contact name
Prof Aizura Syafinaz Ahmad Adlan

Contact details
Obstetrics & Gynaecology Department
University Malaya Medical Centre
Jalan University, Lembah Pantai
Kuala Lumpur
Malaysia
50603
+60123375808
aizuraadlan@gmail.com

Type(s)
Public

Contact name
Dr Hairel Mohd Tarmidzi

Contact details
Obstetrics & Gynaecology Department
University Malaya Medical Centre
Jalan University, Lembah Pantai
Kuala Lumpur
Malaysia
50603
+601112112522
hairel@gmail.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Version 1.0 01-01-2019

Study information

Scientific Title
Post LaparoscopY Pain Reduction Project I (POLYPREP I): Single Strategy of Intraperitoneal Normal Saline Infusion (INSI); A Randomised Controlled Trial

Acronym
POLYPREP I

Study objectives
Intraperitoneal normal saline infusion would reduce post laparoscopy shoulder and abdominal pain

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/03/2019, Medical Research Ethics Committee, University Malaya Medical Center (Lembah Pantai, 59100 Kuala Lumpur, Malaysia; rosmawatib@ummc.edu.my; +603 79494422 ext. 3209 / 2251), ref: 201926-7106.

Study design
Randomised controlled trial single-blind

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Laparoscopic abdominal surgery for a benign gynaecological condition

Interventions

Surgical procedure:
All procedures will be performed under general anaesthesia. Pre-operative prophylactic antibiotics will be given. Subjects will be put in Trendelenburg position at 20 degree with both arms tucked in. Carbon dioxide gas is used as the distension medium. Intra-abdominal pressure of 20 mmHg is achieved with a flow rate of 2L/min, followed by 5mm or 12mm primary trocar insertion at umbilicus. Additional ports are placed as necessary. The distension pressure is then reduced to 15mmHg with a flow rate not exceeding 2L/min throughout the surgery.

Intervention:
At the end of the surgery, the interventional protocols will be carried out as below:
Group A (INSI)
-Patient will be placed in Trendelenburg position (20 degrees). Intraperitoneal normal saline (15 ml/kg) will be infused at the upper part of the abdominal cavity evenly by the surgeon.
-Trocar sleeve valves will be left open during instillation of normal saline to allow carbon dioxide to escape from the abdominal cavity (this procedure usually lasts for approximately 5 minutes).
-The instilled normal saline will be left in-situ.
-Patient will be placed in neutral position at the end of the intervention.

Group B (control)
-Patient will be placed in Trendelenburg position (20 degrees).
-Trocar sleeve valves will be left open for a fixed time of 5 minutes.
-Patient will be placed in a neutral position at the end of the intervention.

After completing the intervention as stated above, instruments and trocars will be removed and abdominal incisions will be closed as per standard procedure. Subjects will receive standard postoperative care in ward and discharged according to the discretion of each managing team.

Subjects will be assigned to two groups at 1:1 ratio using a random-permuted block randomisation algorithm via web-based system (www.randomization.com) by an investigator not involved in subject recruitment. The master list for the randomised treatment allocation sequence will be kept by the same investigator. Concealment will be done by using serially numbered opaque, sealed envelopes; each of these envelopes contained a colour coded paper with the legend ‘INSI’ or control. The next available randomisation number will be assigned to the subject once she consents to participate (during pre-op discussion). The mentioned envelope will be given to study nurses who are not involved in the management of subject upon arrival inside theatre. The envelope will be opened at the end of the surgery, before removal of laparoscopic trocars in the operating room.

Subjects who withdraw from the study before surgery will be replaced by the next consented subject. However subjects who withdraw from the study after surgery will be counted as a dropout and no replacement will be done.

Intervention Type

Procedure/Surgery

Primary outcome measure

Post laparoscopy pain in shoulder and abdomen (upper and lower abdomen) area at 24, 48 and 72 hours after surgery using numeric rating scale (NRS).

Secondary outcome measures

1. Post operative use of analgesia
2. Nausea, vomiting and abdominal distension
3. Time to pass first flatus after surgery
4. Duration of hospital stay

Overall study start date
01/01/2019

Completion date
31/12/2019

Eligibility

Key inclusion criteria
1. Women aged 18 years and above
2. Scheduled for laparoscopic surgery for benign gynaecological condition
3. American Society of Anaesthesiologist (ASA) classification I-II:
ASA I – normal healthy patient
ASA II – patient with mild systemic disease without substantive functional limitations (BMI < 40 kg/m2, well-controlled diabetes mellitus / mild hypertension, mild lung disease)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
68

Total final enrolment
68

Key exclusion criteria
1. Conversion to laparotomy
2. Allergy to non-steroidal anti-inflammatory drugs (NSAID) drugs or paracetamol
3. Pre-operative emphysema / chronic obstructive pulmonary disease (COPD)
4. Women who do not understand the questionnaire
5. Pre-existing shoulder pain
6. Intellectual disability

Date of first enrolment
01/07/2019

Date of final enrolment
31/12/2019

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Centre
Obstetrics & Gynaecology Department
University Malaya Medical Centre
Jalan Universiti
Lembah Pantai
Kuala Lumpur
Malaysia
50603

Sponsor information

Organisation
University Malaya Medical Centre Obstetrics & Gynaecology Department

Sponsor details
Jalan Universiti
Lembah Pantai
Kuala Lumpur
Malaysia
50603
+603-7949 4422
szawiah@um.edu.my

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
Not defined

Funder Name
Investigator initiated and funded

Results and Publications

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

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		05/03/2021	05/03/2021	No	No
Results article		12/04/2012	19/07/2023	Yes	No