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Post laparoscopy pain reduction project

Submission date
19/12/2020

Recruitment status
No longer recruiting

Registration date
26/12/2020

Overall study status
Completed

Last Edited
04/01/2021

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
The purpose of this study is to evaluate the effectiveness of the proposed treatment (intraperitoneal normal saline infusion versus intraperitoneal Ringer Lactate infusion) in reducing pain after the operation. Pain after laparoscopic (or 'key-hole') surgery is common. Although it is less severe than conventional 'open' surgery, patients experience pain over the shoulder and upper abdominal region (which is not related to the skin incision site) particularly in the first 24 h after surgery. Painkillers do not seem to be effective in eliminating this pain.

Intraperitoneal normal saline (NS) infusion (an injection of salt water in the abdomen) has been shown to be effective in one previous study for reducing pain after laparoscopic surgery. Carbon dioxide is used to inflate the abdomen during laparoscopic surgery to provide more space and visibility for surgeons to complete the procedure, however this may remain in the abdomen after the surgery. The remaining carbon dioxide gas in the abdomen will cause an acidic environment in the abdomen and trigger postoperative shoulder and upper abdomen pain. NS has also been shown to be beneficial in removing post laparoscopic carbon dioxide retention and helps reduce post operative pain over the shoulder and abdomen.

On the other hand, intraperitoneal Ringer lactate (RL) solution (another type of salt water) has been used safely as intraperitoneal wash during surgery and is effective in preventing intraperitoneal adhesions (abnormal bonds between the organs and walls of the abdomen that can form following surgery and can cause pain and reduce movement or block organs). Ringer's lactate component is near to human plasma and has less acidic pH as compared to normal saline solution. To date, there is no study to answer whether RL solution could be used to reduce carbon dioxide retention.

The study team aim to generate local research and data to compare NS and RL for pain relief and carbon dioxide retention following laparoscopic surgery.

Who can participate?
Adult women scheduled for laparoscopic surgery for a benign gynaecological indication at University Malaya Medical Centre

What does the study involve?
If they agree to participate, participants will be involved in the study for the 3 days after their

surgery. The doctor will perform some tests and examinations to ensure participants are suitable for the study. If they are deemed suitable, participants will be randomly assigned to one of two treatment groups below, with an equal chance of being assigned to either of the groups:
1. Intraperitoneal normal saline infusion (salt water) will be left inside the abdomen before removing the camera at the end of the surgical procedure
2: Intraperitoneal Ringer Lactate infusion (salt water) will be left inside the abdomen before removing the camera at the end of the surgical procedure
Surgery and routine care before and after surgery will be the same for both groups and for others who did not participate in the study.

After the operation, participants in both groups will be required to fill up the questionnaires, and an explanation of how to complete them will be provided. If participants are discharged sooner than 72 h after their surgery is complete, they will be provided a copy of pain scale with the number 0 to 10 and will be contacted via telephone to complete the questionnaires.

What are the possible benefits and risks of participating?
The study treatments may reduce postoperative pain score and participants may require fewer painkillers.

The previous study did not find side effects from either solution. However, allergic reactions to the above-mentioned solutions which are very rare might occur.

The study products do not contain porcine, bovine, or animal components.

If participants think they have a study-related injury or want information about treatment they are advised to contact: Dr Teing Shu Jun (+60 (0)12 5297948). If participants have any questions about their rights as a participant in this study they are advised to contact: The Secretary, Medical Research & Ethics Committee, Ministry of Health Malaysia (+60 (0)3-2287 4032).

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?
From April 2019 to March 2020

Who is funding the research?
The research is self-funded by the researcher

Main contact:
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Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NMRR-20-9-52565

Study information

Scientific Title
POst LaparoscopY Pain REduction Project (POLYPREP III): intraperitoneal normal saline (INSI) infusion versus intraperitoneal Ringer's lactate (INRL) infusion: a Randomised Control Trial

Acronym
POLYPREP III

Study objectives

The use of intraperitoneal Ringer's lactate has a better outcome in postoperative pain control compared to intraperitoneal normal saline

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/12/2019, Medical Research Ethics Committee, University of Malaya Medical Centre (2nd floor, Kompleks Pendidikan Sains Kejururawatan, Pusat Perubatan Universiti Malaya, Lembah Pantai, 59100 Kuala Lumpur, Malaysia; +60 3-79493209/2251; ummc-mrec@ummc.edu.my), ref: 2019429-7370

Study design
Single centre, single-blind (subject), prospective randomized parallel design study

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Post laparoscopy pain following benign gynaecological surgery, post-surgical pain

Interventions
All women who are scheduled for elective laparoscopic surgery with benign gynaecological indication will be assessed for eligibility one day before the operation date on the gynaecology ward or at the gynaecology clinic before operation date is given. Written consent will be obtained from each subject (or their parent/guardian) and confidentiality assured.

Subjects will be assigned to two groups at a 1:1 ratio using a random-permuted block randomisation algorithm in 2 blocks via a web-based system (www.randomization.com) by an investigator not involved in subject recruitment or in other study procedures. 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’ (for intraperitoneal normal saline, group A) or ‘INRL’ (for intraperitoneal Ringer's lactate, group B). 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.

Post-operation after 1, 2, and 3 days, subjects will be interviewed regarding the post-operative pain score according to a questionnaire. If the subject is discharged after day 1 post-operation, they will be contacted by telephone to be interviewed according to the questionnaires designed by the investigator.

All procedures will be performed under general anaesthesia. Subjects will be put in Trendelenburg position at 20° 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 2 l/min, followed by 5 mm or 10 mm primary trocar insertion at the umbilicus. Additional ports are placed as necessary. The distension pressure is then reduced to 15 mmHg with a flow rate not exceeding 2 l/min throughout the surgery.

At the end of the surgery, the interventional protocols will be carried out as below:
1. Group A (INSI) patients will be placed in Trendelenburg position and receive intraperitoneal normal saline (15 ml/kg) will be instilled at the upper part of the abdominal cavity evenly by the surgeon. Trocar sleeve valves will be left open during the instillation of normal saline to allow carbon dioxide to escape from the abdominal cavity. The instilled normal saline will be left in-situ and the patient will be placed in a neutral position at the end of the intervention.
2. Group B (INRL) patients will be placed in Trendelenburg position and receive intraperitoneal Ringer lactate (15 ml/kg) will be instilled at the upper part of the abdominal cavity evenly by the surgeon. Trocar sleeve valves will be left open during the instillation of Ringer's lactate to allow carbon dioxide to escape from the abdominal cavity. The instilled Ringer lactate will be left in-situ and the 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. The patient will then be transferred to the recovery area. Subjects will receive standard postoperative care in the ward and discharged according to the discretion of each managing team.

A standard regime of analgesia will be given to all subjects, in which intravenous Paracetamol (1 g) and intravenous Parecoxib (40 mg), or suppository diclofenac acid will be given at the end of surgery, followed by a regular dose of oral paracetamol (1 g, every 6 h, for five days) and rescue dose of analgesia (opioids or celecoxib) when needed.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Normal saline solution, Ringer's lactate solution

Primary outcome measure
1. Intensity and incidence of post laparoscopic pain in the shoulder, upper abdomen, and lower abdominal area measured using a participant questionnaire with a 0-10 numerical rating scale (NRS) at 1, 2, and 3 days

Secondary outcome measures
1. Post-operative use of analgesia collected using a participant questionnaire at 1, 2, and 3 days
2. Nausea, vomiting, and abdominal distension measured using a participant questionnaire at 1,

2, and 3 days
3. Time to pass first flatus after surgery collected using a participant questionnaire at 1, 2, and 3 days
4. Duration of hospital stay collected from patient notes at the time of discharge

Overall study start date
04/09/2019

Completion date
28/02/2021

Eligibility

Key inclusion criteria
1. Women aged 18 years and above
2. Scheduled for laparoscopic surgery with a benign gynaecological indication like laparoscopic cystectomy and laparoscopic salpingectomy/salpingoophorectomy at University Malaya Medical Centre
3. American Society of Anaesthesiologists (ASA) classification I-II:
3.1. ASA I is a normal healthy patient, non-smoking, no or minimal alcohol use
3.2. ASA II is a patient with mild systemic disease without substantive functional limitations (such as BMI <40 kg/m², mild lung disease, well-controlled diabetes mellitus or hypertension, current smoker, social alcohol drinker, or pregnancy)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
80

Total final enrolment
80

Key exclusion criteria
1. Conversion to laparotomy
2. Allergy to nonsteroidal anti-inflammatory drugs (NSAIDs), paracetamol, or tramadol
3. Pregnancy
4. Unable to read and sign information sheet and consent form
5. Pre-existing shoulder pain which is based on doctor and clinical report before the study
6. Intellectual disability based on doctor and clinical report
7. Allergy to Ringer’s lactate solution

Date of first enrolment
01/02/2020

Date of final enrolment
28/02/2021

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Centre
Obstetric and Gynaecology Department
Lembah Pantai
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Malaysia
59100

Sponsor information

Organisation
University of Malaya

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ummc-mrec@ummc.edu.my

Sponsor type
Hospital/treatment centre

Website
https://www.ummc-mrec.org/

ROR
https://ror.org/00rzspn62

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer-reviewed journal such as the Journal of minimally invasive gynaecology.

Intention to publish date
01/02/2022

Individual participant data (IPD) sharing plan
The data sharing plans for 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		22/12/2020	04/01/2021	No	Yes
Protocol file	version v1.1	04/09/2019	04/01/2021	No	No