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RESEARCH PROPOSAL FOR MASTER OF MEDICINE

(OBSTETRICS AND GYNAECOLOGY)

DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY

UNIVERSITI MALAYA

TITLE

Post Laparoscopy Pain Reduction Project (POLYPREP III): Intraperitoneal Normal Saline (INSI) Infusion Versus Intraperitoneal Ringer Lactate (INRL) Infusion: A Randomised Control Trial

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1.0 STUDY TITLE

Post Laparoscopy Pain Reduction Project (POLYPREP): Intraperitoneal Normal Saline (INSI) Infusion versus Intraperitoneal Ringer Lactate (INRL) infusion: A Randomised Control Trial

2.0 INTRODUCTION AND LITERATURE REVIEW

Laparoscopic surgery which is also known as keyhole surgery or minimally invasive surgery has been revolutionised over decades. It has popularised and become a treatment of choice. The benefits of having laparoscopic surgery compared to open surgery are reduced blood loss, shorter postoperative ileus, faster recovery, shorter hospital stay and better cosmetic outcome. In facts, one of the greatest advantages of laparoscopic surgery is lesser postoperative pain [1,2].

Despite these benefits, many patient may suffer pain from upper abdomen, back or shoulders, discomfort of port site incision and drain site post laparoscopy[3]. The incidence of the upper abdominal pain occurs in about 90% whereas shoulder pain is ranges from 35-80% [4-8]. The pain may be transient or persist for at least 3 days [4]. The intensity of pain is peak during post operation first few hours and declines after 2 or 3 days [9]. Nowadays, post- laparoscopic pain will not be noticed and treated well due to early discharge.

The aetiology of laparoscopy induced shoulder and upper abdomen pain is multifactorial and not fully understood [10,11]. One of the mechanism is mainly derived from carbon dioxide (CO_2) retention within the abdominal cavity. Riedel et. Al has been proposed that carbonic acid can be transformed from CO_2 within the abdominal cavity by the action of peritoneal carbonic anhydrase[12]. Thus, this acidotic effect of peritoneal pH causes direct damage or irritation of diaphragmatic peritoneal nerve and induce upper abdominal pain[13]. Whereas the shoulder pain is due to the irritation of phrenic nerve by CO_2 retention within the abdomen which causes referred pain in the C4 dermatome [14-16].

Pain relief post-operative is one of the vital parameters to look for in taking care of post operative patient. Therefore, analgesic agents that are frequently used including non-steroidal inflammatory drugs (NSAIDs), opiod and paracetamol which are associated with undesirable side effects and it appear to be ineffective in eliminating post laparoscopic shoulder pain (5,17). Thus, identifying the most effective preventive measures for post laparoscopic pain is paramount.

In view of CO_2 is the foremost factor in both the laparoscopy-induced upper abdomen and shoulder tip pain, the idea of washing out the residual CO_2 might reduce the occurrence or severity of these post operative pain. One of the promising strategies to remove the retention CO_2 involves the use of intraperitoneal normal saline (IPNS) infusion[18-22]. IPNS was first reported by Perry and Tombrello (1993), echoed by Tsimoyiannis, 1998, Suginami et al., (2009), Tsai et al., (2011)with no adverse effects had been reported. By infusion of IPNS, it is thought to dissolve excess CO_2 via physiological buffering system and it may rises the CO_2 and force the CO_2 escape through the port sites [23-27].

Crsytalloid fluids include normal saline (NS) and Ringer's lactate(RL) solution, both are isotonic solution with balanced electrolyte composition. Normal saline has an average pH of 5.0 and osmolarity of 308mOsml/L, while Ringer's lactate has an average pH of 6.5, hypo-osmolar of 272 mOsml/L and has similar electrolytes to the plasma. Ringer's lactate is more physiologically compatible fluid than normal saline [28,29]. When CO2 gas was used for pneumoperitoneum, the intraperitoneal pH was showned to be 6.0 immediately after operation and raised to 6.4-6.7 and 6.8-6.9 on the first and second post-operation days respectively according to Pier A et. Al [30] . As evidence proven above where the peritoneal irritation and phrenic nerve damage are due to the acidic intraperitoneal cavity created by the dissolution of CO2, a solution with more alkaline pH are needed to neutralize the acidic peritoneal environement in order to reduce the peritoneal irritation and phrenic nerve damage which directly lead to postoperative pain. By comparing the pH of normal saline and Ringer's lactate, RL acid base balance is superior to that of normal saline[31,32]. Therefore, Ringer's lactate is better in neutralising the acidic peritoneal environement compared to Normal saline. In additio,RL solution has been used intraperitoneal safely as intraperitoneal wash during surgery and effective in preventing intraperitoneal adhesion(33). Ludovico Muzii et. Al has provened that Ringer's lactate solution remains in the peritoneal cavity longer than tradionally believed whereby estimated intraperitoneal absorption of instilled crystalloids is approximately 30-60ml per hour (34). Since Ringer's lactate solution stay longer than Normal saline intraperitoneally, therefore its effect on reduced pain will be more continuous and persistent until the intraperitoneal Ringer's lactate was absorbed. With all of the above comparison between NS and RL, NS has only been studied and beneficial in removing post laparoscopic CO_2 retention. However, to date, there is no study to answer whether RL solution is another choice of solution to use for eliminate the post laparoscopic CO_2 retention. Thus, it is necessary and clinically relevant to examine the post-laparoscopic pain relieve effects by comparing using intraperitoneal infusion laparoscopically of these two crystalloids .

3.0 OBJECTIVES OF STUDY

To evaluate the effectiveness of intraperitoneal normal saline infusion (INSI) versus intraperitoneal Ringer lactate infusion (INRL) in reducing post gynaecological surgery laparoscopic pain in the shoulder and abdomen.

4.0 RESEARCH HYPOTHESIS

We hypothesise that the use of INRL has better outcome in postoperative pain control compared to INSI.

4.1 ENDPOINTS

4.1.1 Primary Endpoint

Main outcome measured is

a. Post laparoscopic pain in shoulder, upper abdomen and lower abdomen area at 24, 48 and 72 hours after surgery using self-administered questionnaire and scale by the numeric rating scale (NRS).

4.1.2 Secondary Endpoint

a. Post-operative use of analgesia
b. Nausea, vomiting and abdominal distension
c. Time to pass first flatus after surgery
d. Duration of hospital stay

5.0 METHODOLOGY

5.1 STUDY DESIGN

This single centre, prospective single-blind (subject), randomized, parallel design study enrolled patients who have undergo elective benign laparoscopic gynaecological surgery at University Malaya Medical Centre, Kuala Lumpur, Malaysia.

There will be two groups of patients where they will be randomized to one group will receive intraperitoneal normal saline while the other will receive Ringer's lactate solution. Then self-administered questionnaire and pain score will be scaled from the subjects.

5.2 POPULATION OF STUDY

Women who undergoes elective benign laparoscopic gynaecological surgery at University Malaya Medical Centre, Kuala Lumpur, Malaysia.

5.3 INCLUSION CRITERIA

i. Aged 18 years and above
ii. Women who are scheduled for laparoscopic surgery with benign gynaecological indication like laparoscopic cystectomy and laparoscopic salphingectomy/salphingoophorectomy
iii. American Society of Anaesthesiologists (ASA) classification I-II
    a. ASA I – normal healthy patient, non-smoking, no or minimal alcohol use
    b. ASA II – patient with mild systemic disease without substantive functional limitations (BMI <40kg/m2, well-controlled diabetes mellitus/hypertension, mild lung disease) but not limited to current smoker social alcohol drinker, pregnancy, obesity (30<BMI<40, well-controlled diabetes mellitus/hypertension, mild lung disease)

5.4 EXCLUSION CRITERIA

i. Conversion to laparotomy.
ii. Allergy to nonsteroidal anti-inflammatory drugs (NSAIDs), paracetamol or tramadol.
iii. Pregnancy.
iv. Women who do not able to read and sign information sheet and consent form.
v. Pre-existing shoulder pain which is based on doctor & clinical report before the study.
vi. Intellectual disability based on doctor & clinical report
vii. Allergy to Ringer's lactate solution

5.5 SUBJECT WITHDRAWAL & DROP OUT

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. The reasons for a subject withdraw or is withdrawn will be completely reported.

5.6 METHODS

SAMPLING AND RANDOMIZATION

PHASE 1:

All women who are scheduled from 1st February 2020 until 28th February 2021 for elective laparoscopic surgery with benign gynaecological indication will be assessed for eligibility to enter study according to the inclusion and exclusion criteria by researcher one day before operation date gynaecology ward or at gynaecology clinic before operation date is given. Written consent will be obtained from each subject or parent/guardian and confidentiality assured.

Subjects will be assigned to two groups at 1:1 ratio using a random-permuted block randomisation algorithm in 2 blocks via web-based system (www.randomization.com) by an investigator not involved in subject recruitment and 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' or 'INRL' The next available randomisation number will be assigned to the subject once she consents to participate (during pre-op discussion).

PHASE 2:

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.

PHASE 3:

Post operation day 1, 2 and day 3, subjects will be interview regarding the post operative pain score according to the questionnaire. If subject is discharged after day 1 post operation, she

will be called up and interviewed according to the designed questionnaires by the investigator**.**

BLINDING AND COLLECTION OF DATA

It is impossible that the surgeons and anaesthesiologists are masked for this trial. Subjects and postoperative care staffs will be blinded to group allocation. Demographics data, intra-operative data and post-operative complications will be collected by researcher as per case report form (Appendix I). A research assistant who is not involved in recruitment and clinical management of subject will be appointed to collect post-operative pain score, analgesic usage and gastrointestinal disturbance scoring as per Appendix II. If subjects are discharged before 48 hours post-op, a copy of numeric rating scale (NRS) will be provided to subject for reference. This is to ensure accuracy when pain score is collected via telephone.

OPERATIVE TECHNIQUE

All procedures will be performed under general anaesthesia. Subjects will be put in Trendelenburg position at 20 degree with both arm tucked in. Carbon dioxide gas is used as the distension medium. Intra-abdominal pressure of 20mmHg is achieved with a flow rate of 2L/min, followed by 5mm or 10mm 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 (15mls/kg) will be instilled 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.
- The instilled normal saline will be left in-situ.
- Patient will be placed in neutral position at the end of the intervention**.**

•Group B (INRL)

- Patient will be placed in Trendelenburg position (20 degrees). Intraperitoneal Ringer Lactate (15mls/kg) will be instilled at the upper part of the abdominal cavity evenly by the surgeon.
- Trocar sleeve valves will be left open during instillation of Ringer's lactate to allow carbon dioxide to escape from the abdominal cavity.
- The instilled Ringer Lactate will be left in-situ.
- Patient will be placed in 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. Subject will then be transferred to recovery area.
Subjects will receive standard postoperative care in 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 1g and intravenous Parecoxib 40mg or suppository diclofenac acid will be given at the end of surgery, followed by regular dose of oral paracetamol 1g 6 hourly for five days and rescue dose of analgesia (opiods or celecoxib) when needed.

MONITORING AND FOLLOW-UP:

Pain score post operation day 1 and day 2 will be monitored in the ward. If subject is discharged on day 1 post operation, she will be contacted and follow up regarding the post operation pain score**.**

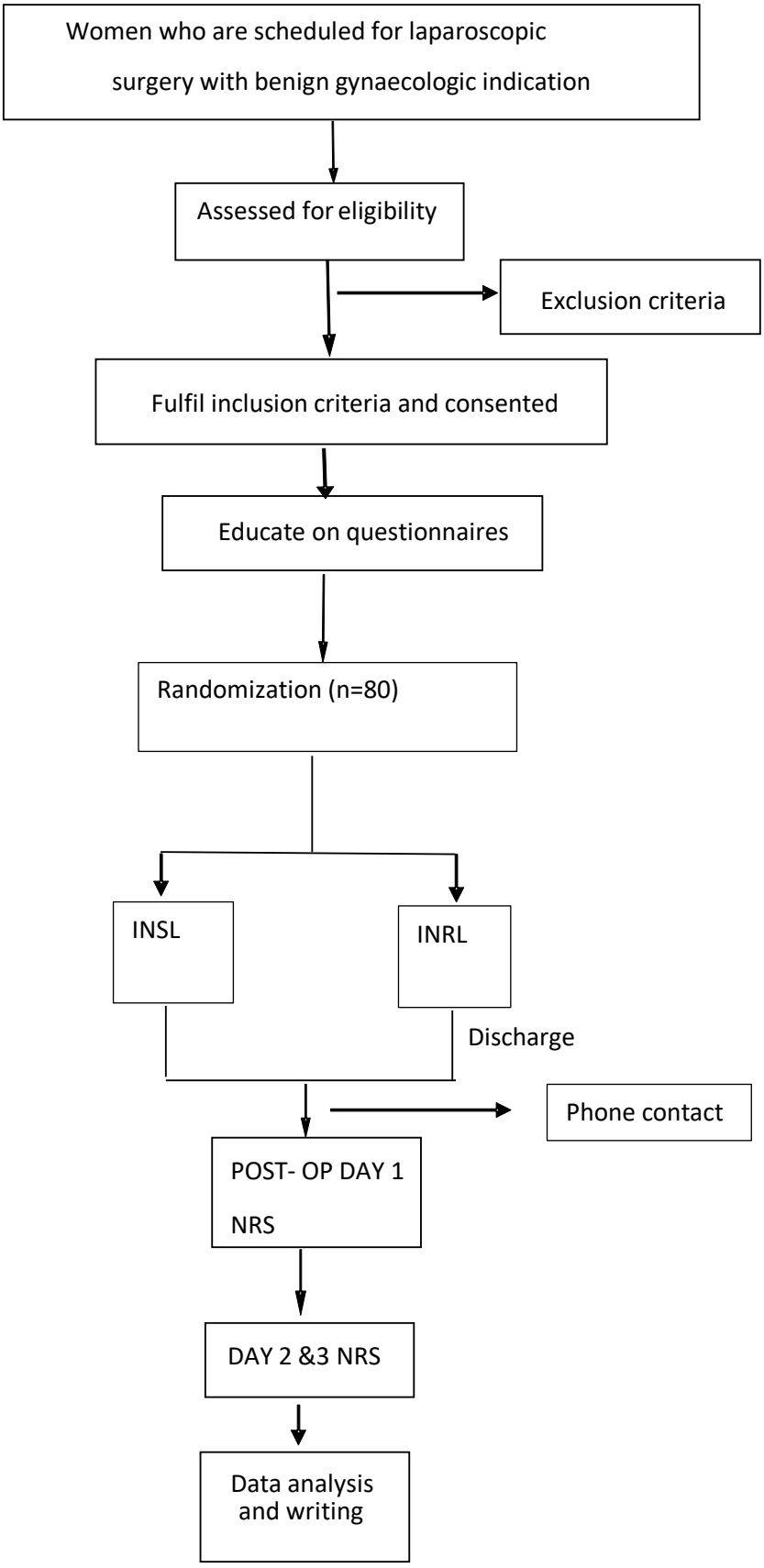
5.7 MEASUREMENTS

The primary outcome of this study is the intensity and incidence of post laparoscopic pain in shoulder, upper abdomen and lower abdominal area at 24, 48, 72 hours after surgery. It will be measured by 0-10 numerical rating (NRS), where 0 = no pain and 10 = worst possible pain. NRS has been adapted by Ministry of Health Malaysia to be one of the pain assessment tools (Ministry of Health Malaysia, 2014). Subjects will be educated pre-operatively regarding questionnaires (Appendix II) which consist of NRS to rate the post-operative pain at rest and movement on specific time and site; occurrence of nausea, vomiting, abdominal distension; time to pass first flatus after surgery and additional analgesia required.

A research assistant who is not involved in recruitment and clinical management of subject will be appointed to collect post-operative pain score, analgesic usage and gastrointestinal disturbance scoring as per Appendix II. Subjects will be contacted via telephone by research assistant if subjects are discharge before 48 hours post-op**.**

Demographics data, intra-operative data and post-operative complications will be collected by researcher as per case report form (Appendix I). Prolonged postoperative paralytic ileus is defined as presence of two or more of the five criteria (nausea or vomiting; inability to tolerate oral diet over past 24hours; absence of flatus over past 24hours; abdominal distension; radiological confirmation) after day 3 of surgery (Vather et al., 2013)**.**

5.8 Study Flow Chart



5.9 ETHICAL CONSIDERATION

This study will be submitted to the UMMC Medical Research Centre and Ethics committee, the local institutional review board for approval. Besides, this study will adhere to the ethical principles that have their origin in the "World Medical Association Declaration of Helsinki", "Malaysian Guidelines for Good Clinical Practice" and applicable regulatory Requirements. Confidentiality will be ensured. All participants will be given an information sheet and written informed consent will be obtained as approval for their participation in the study.

5.10 SAMPLE SIZE CALCULATION

Sample size was calculated with PS software (PS Power and Sample Size Calculations, Version 3.1.6, October 2018, by William D. DuPont and Walton D. Plummer), available on

(http://biostat.mc.vanderbilt.edu/wiki/Main/PowerSampleSize#PS:_Power_and_Sample_Size_Calculation). Based on previous study (Cruz *et al*., 2014) the standard deviation of NRS for post laparoscopic pain was 2.2. To detect a 2 point difference which is the clinical significance difference in NRS (Farrar *et al.*, 2001), 92 subjects (with 23 subjects in each arm) will be needed to detect a 2 point difference with type 1 error of 0.05, power of 95%. Estimating a 20% dropout rate and rounding up, we planned to recruit 80 subjects (40 subjects in each arm).

5.11 STATISTICAL ANALYSIS

Data will be entered into SPSS statistical software version 20. Normal distribution of continuous data will be checked with the one sample Kolmogorov-Smirnov test/Shapiro-Wilk Test. Descriptive statistic will be done for all outcome variables. Differences between groups will be analyzed with unpaired *t* test for continuous variables and the Chi-square test for the binomial variables. Non-normally distributed continuous data will be analyzed with Mann-Whitney U test. Two-by-two categorical data sets will be analyzed with the Fisher exact test and larger categorical data sets with the chi square test

6.0 STUDY DURATION

This study will be conducted from 1st February 2020 until 28th February 2021.

14.0 GANNT CHART

Year	2019	2020												2021		
Month	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
Literature review																
Proposal																
Ethics review																
Data collection																
Analysis																
Writing																

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Appendix II

PATIENT'S ID STICKER	CONTACT NUMBER _____	DATE OF SURGERY _____/_____/_____	RANDOMISATION ID: _____

STUDY TITLE: Post Laparoscopy Pain Reduction Project (POLYPREP III): Intraperitoneal Normal Saline (INSI) versus Intraperitoneal Ringer's Lactate (INRL); A Randomised Control Trial

<u>Demographic Data:</u>

Patient age:

Weight (kg):

Height (cm):

Previous abdominal scar:

<u>DAY 1 (24HOURS) AFTER SURGERY:</u>

PART I: Pain Score Assessment

1. Which part of your body has the most intense pain?

Shoulder ☐ Upper abdominal region ☐ Lower abdominal region ☐

2. Do you need additional pain killer? Yes ☐ No ☐

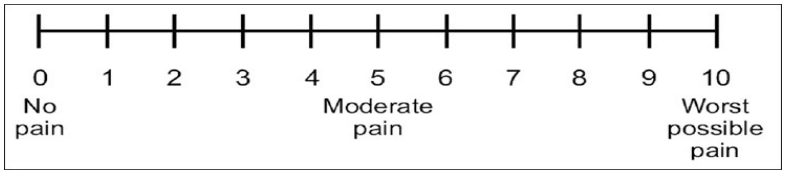
If yes, please provide details as below:

a) Injectable pain killer: Yes ☐ No ☐ Frequency: _____times/day

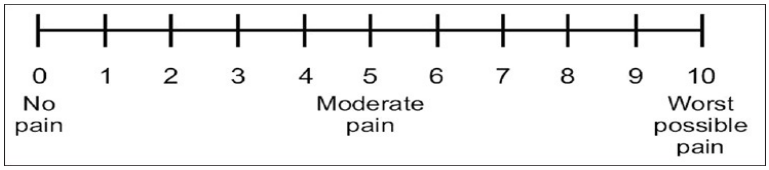
b) Oral pain killer: Yes ☐ No ☐ Frequency: _____times/day

A) Shoulder

3. Which number indicates the pain at your **<u>SHOULDER</u>** at **REST**:



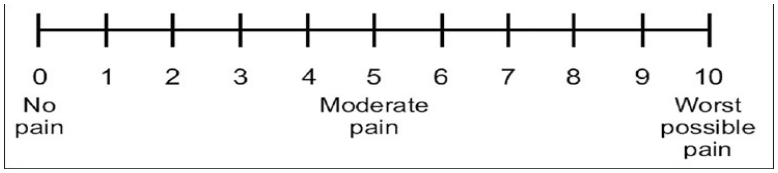
4. Which number indicates the pain at your **<u>SHOULDER</u>** during **MOVEMENT**:



DAY 1 (24HOURS) AFTER SURGERY:

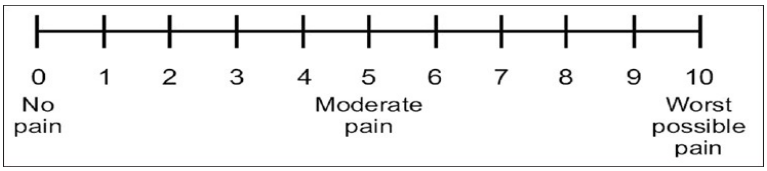
B) Upper abdomen

5. Which number indicates the pain at your **UPPER abdominal region** at **REST**:



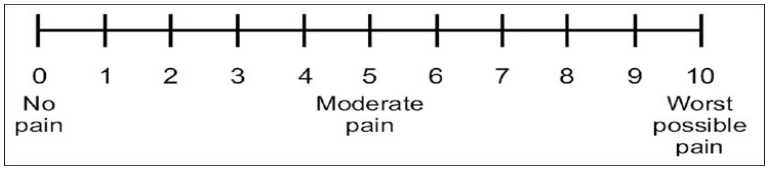
6. Which number indicates the pain at your **UPPER abdominal region** during

MOVEMENT:



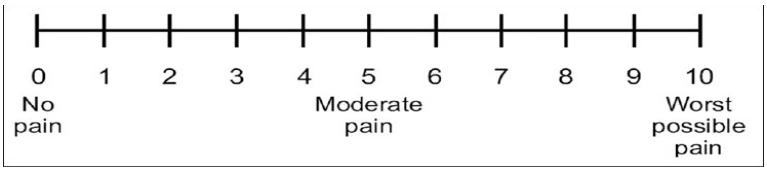
C) Lower abdomen

7. Which number indicates the pain at your **LOWER abdominal region** at **REST**:



8. Which number indicates the pain at your **LOWER abdominal region** during

MOVEMENT:



PART II: Gastrointestinal dysfunction

1. Do you feel nauseated for the past 24 hours?

Yes ☐ No ☐

2. Did you vomit for the past 24 hours?

Yes ☐ No ☐

3. Do you feel that your tummy is distended?

Yes ☐ No ☐

4. In the past 24 hours, are you able to tolerate an oral diet?

Yes ☐ No ☐

5. Did you pass flatus for the past 24 hours?

☐ ☐

Yes No If yes, please state the time when you pass the first flatus.

_____

PATIENT'S ID STICKER	CONTACT NUMBER _____	DATE OF SURGERY _____/_____/_____	RANDOMISATION ID: _____

STUDY TITLE: Post Laparoscopy Pain Reduction Project (POLYPREP III): Intraperitoneal Normal Saline (INSI) versus Intraperitoneal Ringer's Lactate (INRL); A Randomised Control Trial

DAY 2 (48HOURS) AFTER SURGERY:

PART I: Pain Score Assessment

1. Which part of your body has the most intense pain?

Shoulder ☐ Upper abdominal region ☐ Lower abdominal region ☐

2. Do you need additional pain killer? Yes ☐ No ☐

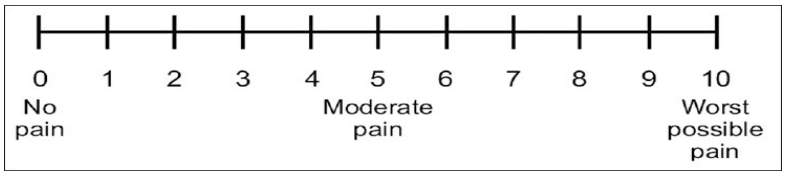
If yes, please provide details as below:

a) Injectable pain killer: Yes ☐ No ☐ Frequency: _____times/day

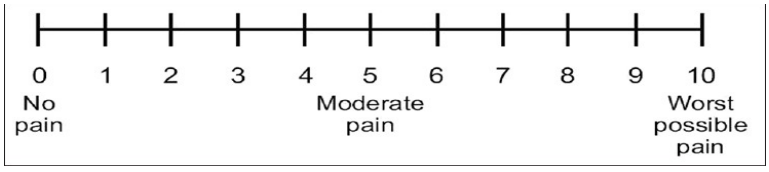
b) Oral pain killer: Yes ☐ No ☐ Frequency: _____times/day

A) Shoulder

3. Which number indicates the pain at your **SHOULDER** at **REST**:



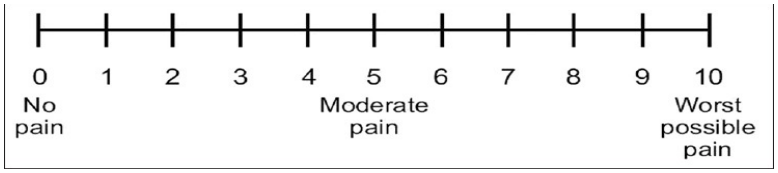
4. Which number indicates the pain at your **SHOULDER** during **MOVEMENT**:



DAY 2 (48HOURS) AFTER SURGERY:

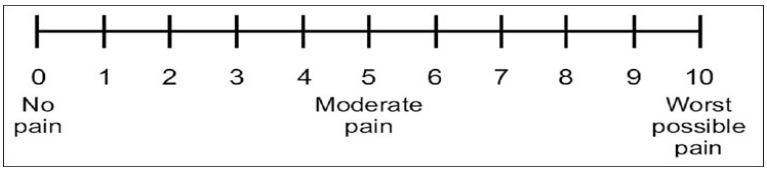
B) Upper abdomen

5. Which number indicates the pain at your **UPPER abdominal region** at **REST**:



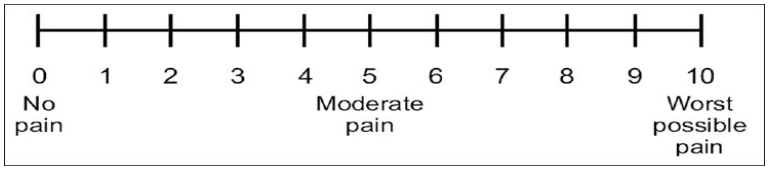
6. Which number indicates the pain at your **UPPER abdominal region** during

MOVEMENT:



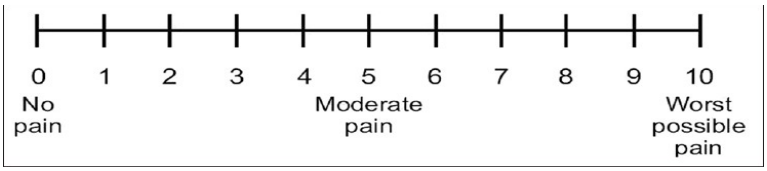
C) Lower abdomen

7. Which number indicates the pain at your **LOWER abdominal region** at **REST**:



8. Which number indicates the pain at your **LOWER abdominal region** during

MOVEMENT:



PART II: Gastrointestinal dysfunction

1. Do you feel nauseated for the past 24 hours?

Yes ☐ No ☐

2. Did you vomit for the past 24 hours?

Yes ☐ No ☐

3. Do you feel that your tummy is distended?

Yes ☐ No ☐

4. In the past 24 hours, are you able to tolerate an oral diet?

Yes ☐ No ☐

5. Did you pass flatus for the past 24 hours?

☐ ☐

Yes No If yes, please state the time when you pass the first flatus.

_____

PATIENT'S ID STICKER	CONTACT NUMBER _____	DATE OF SURGERY _____/_____/_____	RANDOMISATION ID: _____

STUDY TITLE: Post Laparoscopy Pain Reduction Project (POLYPREP III): Intraperitoneal Normal Saline (INSI) versus Intraperitoneal Ringer's Lactate (INRL); A Randomised Control Trial

DAY 3 (72 HOURS) AFTER SURGERY:

PART I: Pain Score Assessment

1. Which part of your body has the most intense pain?

Shoulder ☐ Upper abdominal region ☐ Lower abdominal region ☐

2. Do you need additional pain killer? Yes ☐ No ☐

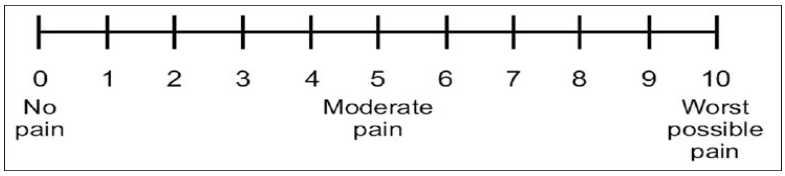
If yes, please provide details as below:

a) Injectable pain killer: Yes ☐ No ☐ Frequency: _____times/day

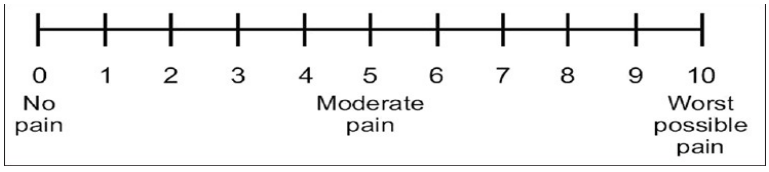
b) Oral pain killer: Yes ☐ No ☐ Frequency: _____times/day

A) Shoulder

3. Which number indicates the pain at your **SHOULDER** at **REST**:



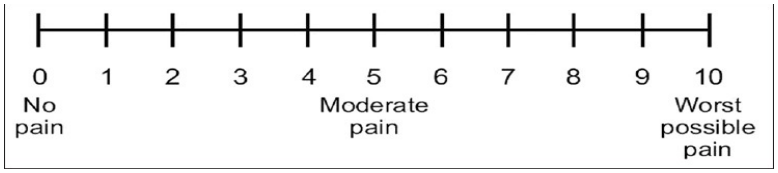
4. Which number indicates the pain at your **SHOULDER** during **MOVEMENT**:



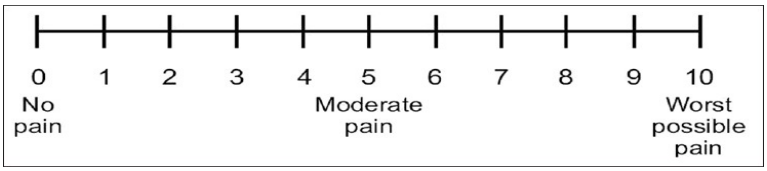
DAY 3 (72 HOURS) AFTER SURGERY:

B) Upper abdomen

5. Which number indicates the pain at your **UPPER abdominal region** at **REST**:

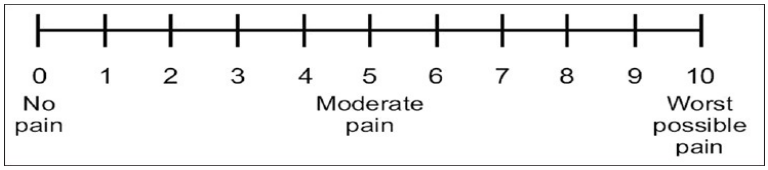


6. Which number indicates the pain at your **UPPER abdominal region** during **MOVEMENT**:

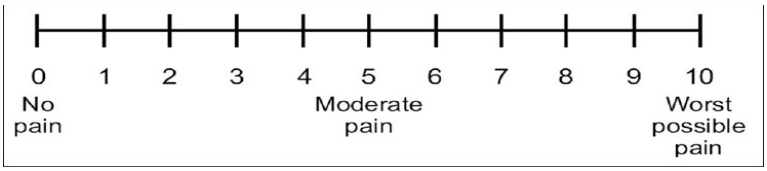


C) Lower abdomen

7. Which number indicates the pain at your **LOWER abdominal region** at **REST**:



8. Which number indicates the pain at your **LOWER abdominal region** during **MOVEMENT**:



PART II: Gastrointestinal dysfunction

1. Do you feel nauseated for the past 24 hours?

Yes ☐ No ☐

2. Did you vomit for the past 24 hours?

Yes ☐ No ☐

3. Do you feel that your tummy is distended?

Yes ☐ No ☐

4. In the past 24 hours, are you able to tolerate an oral diet?

Yes ☐ No ☐

5. Did you pass flatus for the past 24 hours?

☐ ☐

Yes No If yes, please state the time when you pass the first flatus.

_____