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A study to assess factors that may be influenced by reducing pressure in the abdomen during keyhole surgery on the bowel

Submission date
11/05/2017

Recruitment status
No longer recruiting

Registration date
16/05/2017

Overall study status
Completed

Last Edited
15/01/2018

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Colorectal cancer is cancer of the large bowel, which is the lower part of the tubes through which food passes through the body. Keyhole surgery is now considered to be the best way of treating this disease. In keyhole surgery, small cuts are made into the tummy (abdomen) through which the surgeon can pass a viewing system and instruments to do the surgery. This is better for the patient than having a large operation (open surgery) of the abdomen. With keyhole surgery, the patient has to be in hospital for less time and gets over the operation much quicker. During keyhole surgery it is difficult to see what is inside the tummy because everything is squashed together in a confined space. The surgeon gets round this by passing a gas through the keyhole to cause pressure in the tummy. This pushes the organs apart and by changing the patients position, makes surgery easier. Carbon dioxide is the gas most often used because it is safer and relatively cheap. Some patients such as the elderly, those who are obese and those with lung problems may be affected by the increased pressure in the tummy and the carbon dioxide itself. New equipment known as VTS (valveless trocar system) is available which claims to make it easier for the surgeon to see to do the surgery and therefore allows the pressure in the tummy to be reduced. This is better for both the patient and the surgeon. In order to assess the VTS a trial will have to be carried out in the future to compare surgery using it and surgery using the current equipment. Before this is possible, it is necessary firstly to identify what can be measured and compared using the two methods, and then to do a small pilot study. The aim of this study is to identify what measurements can be collected during the keyhole surgery.

Who can participate?
Adults aged 18 and older who are undergoing laparoscopic resection for colorectal neoplasia.

What does the study involve?
After consenting to join the study, the researcher collects the data points outlined in the outcomes section during surgery and the patient's progress following surgery, such as their pain scores up to the day of discharge. The participant undergoes the planned treatment proposed by the clinical team and has routine observations as per the hospital usual practice. No additional interventions or tests are performed for this study. The total duration of follow-up is

up to the day of discharge from hospital following their bowel resection, which is usually between 5 to 10 days.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Churchill Hospital (UK)

When is the study starting and how long is it expected to run for?
December 2015 to July 2017

Who is funding the study?
Conmed (UK)

Who is the main contact?
Dr Marta Penna (Scientific)

Contact information

Type(s)
Scientific

Contact name
Dr Marta Penna

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Contact details
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OX3 7LE

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11821

Study information

Scientific Title
Reducing Intra-Abdominal Pressure in Laparoscopic Colorectal Surgery: A feasibility study

Acronym
RAPCo

Study objectives
Aims and objectives:
1. To determine if significant differences can be measured through intra-operative and postoperative outcomes that reflect a change in the intra-abdominal pressures during laparoscopic colorectal surgery
2. To determine the range of any differences in a number of variables, in order to identify the best primary outcome for future research studies
3. To determine if the valveless trocar system (VTS) is able to reliably and safely offer a way of reducing the intra-abdominal pressure (IAP) during laparoscopic surgery

Hypothesis:
1. A reduction in intra-abdominal pressures during laparoscopic surgery will have an impact on carbon dioxide elimination and surgical operative flow with a subsequent improvement in patient outcomes
2. The VTS offers a more reliable and safer method of reducing the IAP during laparoscopic surgery compared to conventional insufflation techniques

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wales Research Ethics Committee 1, 30/03/2016, ref: 16/WA/0070

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Laparoscopic colorectal surgery

Interventions
Patients that meet the inclusion criteria for the study will be invited to take part and provided with a written information sheet. If the patient consents to participating, the researcher will collect the data points outlined in the outcomes section during surgery and the patient's progress following surgery, such as their pain scores up to the day of discharge. The patient will undergo the planned treatment proposed by the clinical team and have routine observations as per the hospital usual practice. No additional interventions or tests are performed for this study. The total duration of follow-up is up to the day of discharge from hospital following their bowel resection, which is usually between 5 to 10 days.

Intervention Type
Procedure/Surgery

Primary outcome measure
Feasibility is measured by the number and type of variables that can be reliably recorded at 10 minute intervals during laparoscopic colorectal surgery and during post-operative recovery until discharge from hospital.

Secondary outcome measures
1. Intra-operative cardiorespiratory effects are measured by the anaesthetic machine monitoring system at 10 minute intervals.
2. Intra-operative surgical efficiency is measured at 10 minute intervals by:
2.1. Observing the number of times the laparoscope is cleaned,
2.2. Observing the number of times the laparoscopic ports are opened to remove gas
2.3. The intra-abdominal pressure established by the insufflation system
2.4. Recording the total operative time
3. Post-operative pain is measured by a visual analogue pain scale once a day for five days following surgery
4. Post-operative complications are recorded from patient note review the day after patient discharge from hospital

Overall study start date
07/12/2015

Completion date
15/07/2017

Eligibility

Key inclusion criteria
1. Aged18 years or over
2. Male and female
3. Participant willing and able to give consent for participation
4. Able to provide informed consent
5. Undergoing laparoscopic high anterior resection for colorectal neoplasia

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
12

Key exclusion criteria
1. Conversion to open procedure or midline wound
2. Creation of diverting loop ileostomy

Date of first enrolment
18/05/2016

Date of final enrolment
30/03/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Churchill hospital
Oxford University Hospitals NHS Foundation Trust
Old Road
Headington
Oxford
United Kingdom
OX3 7LE

Sponsor information

Organisation
Oxford University Hospitals NHS Foundation Trust

Sponsor details
Research and Development Department
Joint Research Office

Block 60
Churchill Hospital
Oxford
England
United Kingdom
OX3 7LE

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03h2bh287

Funder(s)

Funder type
Industry

Funder Name
Conmed

Results and Publications

Publication and dissemination plan
Results will be published in a peer-reviewed journal.

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

Intention to publish date
15/07/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No