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Comparing Laproscopically delivered Local Anaesthetic Transversus Abdominis Plane Block to Infiltration of local anaesthetic to the ports wounds

Submission date
11/03/2014

Recruitment status
No longer recruiting

Registration date
22/04/2014

Overall study status
Completed

Last Edited
06/10/2015

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
The new laparoscopic Transversus Abdominis Plane (TAP) Block technique is more reliable, solely performed by surgeons, and is supposed to replace the ultra sound-guided method. The latter is time-consuming, need ultra sound skills and is usually done by anaesthetists. Previous reports have shown advantage for the ultra sound -guided TAP block in controlling postoperative pain for several types of abdominal surgery. This study will be the first to evaluate the new method and comparing it with the current practice.

Who can participate?
Adult patients undergoing elective laparoscopic cholecystectomy (gallbladder removal).

What does the study involve?
The surgery will be performed by one of four general surgeons following standardized surgical approach under general anaesthesia, while the TAP Block will be done by one of two surgeons who are familiar with the technique. The intra-abdominal pressure will be set at the same level (12 mm Hg) for all patients.
Participants will be randomly allocated to one of two groups: the test group or the control group.
Test group: The TAP block will be performed bilaterally at four points using a blunt needle at the start of the surgery (the MAX line, mid-point between iliac crest and Subcostal margin, and the anterior axillary line just below the Subcostal margin). All the procedure will be performed under visualization (by the laparoscope). Digital pressure will applied to define the site of injection. The needle will be inserted blindly at the site of injection using till it is visible at the level of the peritoneum. Then the needle will be withdrawn gently for about 0.5 cm, and the injection will be employed. The site of injection will be inspected from within the peritoneal cavity to make sure that no intra-peritoneal injection was done. The presence of internal bulge (Doyle's bulge) is

regarded as the definitive point of the procedure.
Control group: Local periportal infiltration will be done at the four ports before the insertion of ports.

What are the possible benefits and risks of participating?
Risks involved would be same as local anaesthetic injections including bleeding, infection, toxicity, and allergic reactions. Possible benefits would be a better pain control if the TAP Block proves to be superior.

Where is the study run from?
The study will be conducted under the responsibility of Department of Surgery and the Department of Anaesthesia, Mayo General Hospital, Ireland

When is the study starting and how long is it expected to run for?
May 2013 to May 2014

Who is funding the study?
Mayo General Hospital, Ireland

Who is the main contact?
Mr Ghassan Elamin
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Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Efficacy of a Laparoscopically delivered Transversus Abdominis Plane Block Technique During Elective Laparoscopic Cholecystectomy; a Prospective Double Blind Randomized Trial

Study objectives

A newly developed technique of TAP block solely performed by surgeons as described by: Chetwood et al. Laparoscopic assisted transversus abdominis plane block: A novel insertion technique during laparoscopic nephrectomy. Anesthesia 2006; 66: 311-22.

It will be used postoperative pain relief following laparoscopic cholecystectomy.

Our alternative hypothesis is that laparoscopic-assisted four-points TAP block is better than the periportal wound infiltration in controlling the postoperative pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Mayo General Hospital Clinical Research Ethics Committee, 10/04/2013, ref: MGH/CR/145-13

Primary study design
Interventional

Study design
Single-centre interventional prospective randomized double-blinded parallel trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Laparoscopic cholecystectomy

Interventions
Test group intervention : Laparoscopic-assisted transversus abdominis plane (TAP) block, using 50 mls of 0.25% Bupivacaine at four points, and 20 mls of saline as peri portal infilteration.

Control group intervention: peri portal infiltration with 20 mls of 0.5% Bupivacaine, with injecting 50 mils of saline at the TAP space using the four points.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome(s)
Pain score at rest and while coughing using the numerical Visual Analog Scale (VAS) at 1, 3, 6 hrs.

Key secondary outcome(s)
1. Analgesics requirements (paracetamol and NSAID).
2. Nausea and vomiting
3. Pain scoring will be recorded using VAS at 12, 24 hrs.

Completion date
01/04/2014

Eligibility

Key inclusion criteria
1. All consecutive ASA grade I-II patients undergoing elective laparoscopic cholecystectomy
2. Age 18 - 85

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Emergency laparoscopic cholecystectomy
2. ASA grade III, IV, V
3. Converted to open procedures
4. Coagulopathy.
5. Significant liver or renal disease
6. Allergy to Bupivacaine
7. Diagnosis of 'chronic pain syndrome'
8. Known alcohol or substance abuse within the last 6 months.
9. Daily Opioid intake.
10. Abdominal drainage

Date of first enrolment
01/05/2013

Date of final enrolment
01/04/2014

Locations

Countries of recruitment
Ireland

Study participating centre

4 Blackfort Avenue
Castlebar
Ireland
Co. Mayo

Sponsor information

Organisation
Mayo General Hospital (Ireland)

ROR
https://ror.org/02z8t9146

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Mayo General Hospital (Ireland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2015		Yes	No