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The use of local anaesthetic in laparoscopic inguinal hernia repair: a randomised clinical trial

Submission date
06/12/2012

Recruitment status
No longer recruiting

Registration date
28/02/2013

Overall study status
Completed

Last Edited
22/06/2016

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims:
Inguinal hernias result from protrusion of abdominal contents through the inguinal canal in the groin region and are common. Surgery to repair inguinal hernias is one of the most common operations performed in the UK. The surgery can be done by an open traditional method, which involves repairing the hernia through an incision (cut) in the groin, or through a keyhole method (laparoscopic repair). One advantage of keyhole surgery is that it is generally associated with less pain following surgery, although many patients still experience significant pain. This study is looking only at the keyhole method and is trying to establish if there is any additional benefit of administering local anaesthetic in a specific fashion to the internal lining of the abdomen (the peritoneum). All patients will receive local anaesthetic to the port sites (where the keyhole instruments are inserted), the only variable will be whether additional local anaesthetic is given to the lining of the abdomen. The aim of our study is to establish if there is a benefit of instilling local anaesthetic to the peritoneum during laparoscopic inguinal hernia surgery. Although some surgeons perform this
routinely, previous studies have not shown a clear benefit of the technique.

Who can participate?
Any adult patients undergoing elective groin hernia surgery; both principal types of laparoscopic repair will be included [i.e. totally extra-peritoneal (TEP) and trans abdominal preperitoneal (TAPP) repairs].

What does the study involve?
The patients recruited into the study will have the same operation as another patient who is not recruited undergoing the same procedure. The difference will be at the end of the operation, when they will receive either a type of local anaesthetic or a harmless salt solution (50ml). Whether they receive the local anaesthetic or salty solution will be determined at random prior to the procedure. Patients will be asked to rate the severity of their pain following their operation. They will be contacted at 4-6 weeks following the
operation and again at one year. We hope to recruit 160 patients in total.

What are the possible benefits and risks of participating?
The study may show a benefit of giving local anaesthetic differently and as such help patients

undergoing the same procedure in the future.
There is a risk of side effects of local anaesthetics when they are given in high doses but we will not exceed the maximum recommended dose based on patients body weight. There is a theoretical risk of causing a temporary anaesthesia to one of the main nerves (the femoral nerve) that pass through the groin region into the thigh; if this did occur it could potentially delay the discharge of the patient. Patients will be contacted at approximately 1 month and 1 year following their surgery they may find this useful to provide feedback or discuss any concerns that they may have, as follow-up is not routine following this type of surgery.

Where it the study run from?
The study centre will be in Ysbyty Gwynedd, which is a district general hospital in North Wales, UK. Only patients operated on within the hospital will be recruited into the trial.

When is the study starting and how long is it expected to last for?
It is anticipated to start recruiting for the study in early 2013 and recruitment will hopefully be complete by mid-2014. The study will be complete one year following recruitment of the final participant.

Who is funding the study?
Betsi Cadwaladr University Health Board

Who is the main contact?
Mr Stephen Sammut, stephen.sammut@wales.nhs.uk
Mr Anil Lala, anil.lala@wales.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Mr Stephen Sammut

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.2

Study information

Scientific Title
A single-blind randomised trial to assess whether the application of local anaesthetic versus placebo to the peritoneum during laparoscopic inguinal hernia surgery alters the post-operative pain intensity or analgesic requirments in adults

Acronym
LALA

Study objectives
There is no difference in either pain intensity or analgesic requirements following surgery in patients who undergo laparoscopic repair of an inguinal hernia when additional local anaesthetic is applied to the peritoneum.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North Wales Research Ethics Committee - West, 23/07/2012, ref: 12/WA/0227

Study design
Single-blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact stephen.sammut@wales.nhs.uk to request a patient information sheet

Health condition(s) or problem(s) studied
Post operative pain following laparoscopic inguinal hernia surgery

Interventions
Levobupivacaine (0.25%) will be compared to placebo (0.9% sodium chloride). A total of 50ml of study solution will be administered to the peritoneum; the proportion of levobupivacaine administered will depend on the patients body weight. All patients will receive 10ml of 0.25% levobupivacaine to the port sites.

Intervention Type

Other

Phase
Not Applicable

Primary outcome measure
1. Perceived pain on movement or coughing measured on a VAS scale at one, two and four hours post surgery
2. Total dosage of Fentanyl administered in post-operative period

Secondary outcome measures
1. Perceived pain intensity on movement or coughing at other time points during the first post-operative week (measured at 8 hours, 24 hours and then daily)
2. Use of rescue or break-through medication for pain during the first week post-operatively. (All patients will be given a prescription of paracetamol to take regularly, any pain medication used over-and-above this will be classed as rescue medication.)
3. Time to discharge criteria being met

Overall study start date
07/01/2013

Completion date
07/02/2014

Eligibility

Key inclusion criteria
1. Age 18 years or older
2. Elective procedure
3. Suspected inguinal hernia
4. Ability to give informed consent
5. At least 24 hours between decision to operate and operation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
160

Key exclusion criteria

1. History of allergy or sensitivity to local anaesthetics
2. Treatment for chronic pain or long-term analgesic use
3. Conversion to an open repair or laparotomy during the procedure

Date of first enrolment
07/01/2013

Date of final enrolment
07/02/2014

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Department of General Surgery
Bangor
United Kingdom
LL57 2PW

Sponsor information

Organisation
National Health Service in Wales (UK)

Sponsor details
c/o Dr Tony Shambrook
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LL57 2PW

Sponsor type
Government

Website
http://www.wales.nhs.uk/

ROR
https://ror.org/04a496k07

Funder(s)

Funder type
Government

Funder Name
Betsi Cadwaladr University Health Board (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration