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Transversus Abdominis Plane Block after laparoscopic live donor nephrectomy

Submission date
14/06/2010

Recruitment status
No longer recruiting

Registration date
11/08/2010

Overall study status
Completed

Last Edited
12/12/2012

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims.
Keyhole (laparoscopic) live donor kidney removal (nephrectomy) is now a well-established operation in the UK and Leicester was the first unit in the UK to perform this operation and has now carried out more than 400 of these procedures. The laparoscopic technique reduces post-operative pain and the need for pain relieving medication (analgesics) compared to the traditional open operation to remove kidneys, which was performed through quite a large incision. Nonetheless, some patients still require a reasonable amount of pain relieving medication, including intravenous injections of morphine after laparoscopic nephrectomy. We wish to study methods of decreasing the amount of post-operative pain even further.
We would like to investigate the use of a local anaesthetic technique called the transversus abdominis plane (TAP) block. This is a method of anaesthetising or numbing the nerve endings in the abdominal wall at the site of the operation incisions. It involves injecting a local anaesthetic agent into this region after the patient has gone to sleep under general anaesthetic and before the surgery begins. Previous studies have shown that this technique can reduce pain after operations such as caesarean section but there are no studies, so far, in patients undergoing kidney donation.

Who can participate?
Every patient over 18 years that has completed the full work-up for laparoscopic donor nephrectomy and is eligible will be approached for the trial. A total of 50 patients, 25 in each group will be required for the study.

What does the study involve?
In this study, patients undergoing a laparoscopic donor nephrectomy at Leicester General Hospital will be randomly allocated to have either the TAP block, with local anaesthetic (Bupivacaine), or a similar procedure with an inert salt solution (saline) that does not contain any anaesthetic (the control group). The study will be a so-called blinded one in which the patient, the surgeon and the anaesthetist are unaware whether local anaesthetic has been used or not in a particular patient.
Outcomes of the study will be judged primarily on the amount of pain relief that is required and the level of pain patients experience after surgery. Recover will also be assessed and any nausea, vomiting and drowsiness recorded. The duration of hospital stay and time to the

introduction of free oral fluids and first solid food will also be recorded. Blood samples will also be taken to assess the effects of surgery.

What are the possible benefits and risks of participating?
This study will help to determine if the TAP block procedure is beneficial to patients undergoing laparoscopic live donor nephrectomy.
Both Bupivacaine anaesthetic and normal saline are routinely used in clinical practice and should cause no adverse effects. The TAP block procedure will be performed by a Consultant Anaesthetist who is experienced in the technique and giving anaesthetics for kidney donation. As the TAP block involves injections into the skin, it is possible that this will cause a small amount of bruising in the region but this is likely to be very minor. Local anaesthetics do have some adverse effects if they are injected directly into blood vessels. In the unlikely event of this happening, it is possible that there could be effects on the heart and on the nervous system. Precautions are taken to prevent injection of anaesthetics into blood vessels and the injections will also be performed using ultrasound guidance which, again, makes the procedure safer. There will be no long term risks from taking part in this study.

Where is the study run from?
Leicester General Hospital

When is the study starting and how long is it expected to run for?
The study will start in June 2010 and end in June 2012

Who is funding the study?
The University of Leicester, Transplant Department

Who is the main contact?
Professor Michael Nicholson
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Contact information

Type(s)
Scientific

Contact name
Prof Michael Nicholson

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
UHL 10883

Study information

Scientific Title
A randomised controlled trial of Transversus Abdominis Plane Block after laparoscopic live donor nephrectomy

Acronym
TAP Block Trial

Study objectives
The hypothesis to be tested in this study is that the use of a transversus abdominis plane (TAP) block will reduce post-operative pain and analgesic requirements in patients undergoing laparoscopic live donor nephrectomy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leicestershire, Northamptonshire and Rutland Ethics Committee 1 approved on the 8th June 2010 (ref: 10/H0406/12)

Study design
Randomised single centre double-blinded placebo 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 use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Post-operative pain

Interventions

Patients will be randomised into one of two groups:
Group A: Bupivacaine local anaesthetic 20 ml 0.375% injected into the transversus abdominis plane at two sites before surgery
Group B: Placebo control; normal saline 20 ml 0.9% injected into the transversus abdominis plane at two sites before surgery

Follow up period of 7 days.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Total post-operative morphine requirement: post-operative analgesic use will be recorded by the nursing staff and pain team using the standard PCAS form. This will include the total dose of morphine used in mg.
2. Daily post-operative pain levels recorded using visual analogue and verbal response scales: 100 mm line with no pain at all written at the left hand (zero) end and worst pain imaginable written at the right hand (100) end. 0 = no pain at rest or movement; 1 = no pain at rest, slight at movement; 2 = intermittent pain at rest, moderate on movement; 3 = continuous pain at rest and severe on movement.
3. Total duration of PCAS use: post-operative analgesic use will be recorded by the nursing staff and pain team using the standard PCAS from. This will include the duration of PCAS use in hours.

Secondary outcome measures
1. Daily post-operative nausea and vomiting recorded using visual analogue and verbal response scales. 0 = no nausea and vomiting at rest or movement; 1 = no nausea and vomiting at rest, slight at movement; 2 = intermittent nausea and vomiting at rest, moderate on movement; 3 = continuous nausea and vomiting at rest and severe on movement.
2. Daily post-operative sedation recorded and scored as following: 0 = none, patient is alert; 1 = mild, awake but drowsy; 2 = moderate, asleep but rousable; 3 = severe, unrousable.
3. Adverse events caused by the TAP block procedure. These will include evidence of inflammation or infection at the administration sites or adverse effects of the local anaesthetic agent or saline.
4. Duration of post-operative stay. Patients will make their own decision about fitness for discharge from hospital. This decision will not be affected by the views of the medical and nursing team, except in the event of complications.
5. Time to the introduction of free oral fluids and the first solid food. Patients will make their own decision about the intake of fluids and solids. This decision will not be affected by the views of the medical and nursing team, except in the event of complications.
6. Timed up and go. Patients are timed as they rise from a chair, walk 3 metres, turn, walk back and sit. This will be measured before surgery and on post-operative days 1 and 3.
7. Grip strength. A hydraulic Hand Dynamometer is used to measuring grip strength (kg). The scores of 3 successive trials using the right and left hand will be measure before surgery and on each post-operative day until day 7 or at discharge, whichever is sooner.
8. Inflammation, cytokines (IL-1, IL-6 and TNF alpha). A blood sample will be taken pre-operatively and post-operatively at 6, 24 and 48 hours in addition to routine daily blood samples. The blood will be centrifuged and the plasma stored at -80°C until analysed.

Overall study start date
23/06/2010

Completion date
23/06/2012

Eligibility

Key inclusion criteria
Patients will be eligible for the trial if ALL of the following criteria are met:
1. Aged 18 years or over, either sex
2. American Society of Anaesthesiology (ASA) grade 1 or 2
3. Individuals who have completed the full work-up for laparoscopic donor nephrectomy, including an assessment by the Human Tissue Authority
4. Written, signed informed consent to the trial

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
Patients will NOT be eligible for the trial if ANY of the following criteria apply:
1. A history of relevant drug allergy
2. Patients receiving medical therapies considered to result in tolerance to opioids
3. Any condition which, in the opinion of the investigator, makes the patient unsuitable for entry into the study

Date of first enrolment
23/06/2010

Date of final enrolment
23/06/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Transplant Group
Leicester
United Kingdom
LE5 4PW

Sponsor information

Organisation
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Sponsor type
University/education

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ROR
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Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospitals of Leicester NHS Trust (UK)

Funder Name
University of Leicester (UK)

Alternative Name(s)
UoL

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/09/2012		Yes	No