

Comparison of the effect on post-operative pain, patient satisfaction and the incidence of chronic pain by the use of either a transversus abdominis plane nerve block or a standard regime with morphine in patients undergoing surgery for total abdominal hysterectomy

Submission date 30/09/2009	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 14/10/2009	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 12/06/2014	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

08031RM-T

Study information

Scientific Title

Comparison of the effect of transversus abdominis plane block or conventional analgesia on pain scores, patient satisfaction and incidence of chronic pelvic pain after total abdominal hysterectomy: a randomised double-blind controlled trial

Study objectives

Is there a significant difference in post-operative pain scores in patients undergoing total abdominal hysterectomy who have received bilateral transversus abdominis plane blockade compared to a standard post-operative analgesia regime?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Health and Social Care Research Ethics Committee (HSC REC 2) (Northern Ireland) approved on the 12th August 2008 (ref: 08/NIR02/75)

Study design

Randomised controlled double blind 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

Total abdominal hysterectomy

Interventions

Patients will be randomised to receive either a bilateral transversus abdominus plane block (TAPB) using 1 mg/kg 0.375% levobupivacaine up to a maximum of 20 ml bilaterally in addition to a standard analgesia regime of patient controlled morphine (1 mg/ml maximum 12 ml/hr) and intravenous paracetamol (1 g 6-hourly). Patients randomised to receive a standard analgesia regime only will have 1 ml of 0.375% levobupivacaine injected into the area where the TAPB would normally be performed in order to maintain the double blind nature of the trial.

Added 09/08/2011: Trial closed early due to low recruitment secondary to change in surgical technique - 30 patients recruited in total.

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome measure

The reduction in visual analogue scores (VAS) in the post-operative period for patients undergoing total abdominal hysterectomy.

Secondary outcome measures

1. Usage of morphine sulphate in the post-operative period
2. Incidence of nausea and/or vomiting within the first 48 hours after surgery
3. Measurement of oxygen saturations without supplemental oxygen in both groups in the post-operative period
4. Incidence of complications associated with the analgesia techniques in both groups
5. Patient satisfaction with analgesia technique
6. Incidence of chronic pelvic pain at 3 months

Overall study start date

01/11/2008

Completion date

01/02/2010

Reason abandoned (if study stopped)

Participant recruitment issue

Eligibility

Key inclusion criteria

1. American Society of Anaesthesiologists (ASA) class I - III
2. Patients able to give written informed consent
3. Patients requiring total abdominal hysterectomy
4. Female patients aged 18 years and over

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

40 participants - 20 randomised to each group

Key exclusion criteria

1. Patients requiring total abdominal hysterectomy secondary to neoplasia
2. History of allergy to any of the medications used in the study
3. Pre-operative use of opiates
4. Patients unable to use patient controlled analgesia system

Date of first enrolment

01/11/2008

Date of final enrolment

01/02/2010

Locations

Countries of recruitment

Northern Ireland

United Kingdom

Study participating centre

Department of Anaesthetics & Intensive Care Medicine

Belfast

United Kingdom

BT12 6BJ

Sponsor information

Organisation

Belfast Health and Social Care Trust (UK)

Sponsor details

Grosvenor Road

Belfast

Northern Ireland

United Kingdom
BT12 6BA

Sponsor type

Hospital/treatment centre

Website

<http://www.belfasttrust.hscni.net>

ROR

<https://ror.org/02tdmfk69>

Funder(s)

Funder type

Government

Funder Name

Belfast Health and Social Care Trust (UK) (ref: 08031RM-T)

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