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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	Recruitment status	[ ] Prospectively registered
30/09/2009	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
14/10/2009	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/06/2014	Surgery	[ ] 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 contolled 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