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 protocolNot provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

- 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 postoperative 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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

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

United Kingdom

Northern Ireland

Study participating centre

Department of Anaesthetics & Intensive Care Medicine

Belfast
United Kingdom

BT12 6BJ

Sponsor information

Organisation

Belfast Health and Social Care Trust (UK)

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

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?

Participant information sheet
Participant information sheet
11/11/2025 No Yes