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Post operative pain control after abdominal gynaecological surgery using pump-releasing local anaesthetic for 24 hours continuously

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 04/04/2016	**Condition category** Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0021108740

Study information

Scientific Title

Post operative pain control after abdominal gynaecological surgery using pump-releasing local anaesthetic for 24 hours continuously: a prospective, double-blind, randomised, placebo-controlled study

Study objectives
To evaluate whether administering local anaesthetic to the wound area using an infiltration catheter, with a pump releasing system, for 24 hours following surgery will reduce the amount of post operative pain experienced by patients, their opioid consumption and subsequent delayed gastric emptying.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Signs and Symptoms: Pain

Interventions
The surgery will be performed under general anaesthetic induced with fentanyl and propofol. Vecuronium will be administered to facilitate tracheal intubation and for neuromuscular block during surgery. Diclofenac 100 mg will be administered per rectum at the end of the operation. Before the wound is closed a single infiltration catheter which is 1.2 mm in diameter with 90 side holes will be placed between the rectus sheath and subcutaneous layer along the transverse incision. Following the operation patients will be randomised into either an experimental or placebo controlled group using computer generated random numbers. Those in the experimental group will receive marcain 0.5% every 4 hours for 24 hours through the catheter. The placebo controlled group will receive Na-Saline in the same regime. Post-operatively, if patients complain of pain or ask for analgesics morphine will be administered and recorded using a PCA (patient controlled analgesia) device. The patients' pain will be assessed 4, 8, 12, 24, 36, 48 and 72 hours post operatively, at rest during coughing and when mobilising from supine to sitting position in bed. Gastric emptying will also be monitored. Any complication including wound infection will be recorded.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)

1. Post operative pain at 4, 8, 12, 24, 36, 48 and 72 hours while at rest, coughing and mobilising from supine to sitting position in bed, assessed using a 10 point visual analogue scale.
2. Gastric emptying will be recorded on a trial sheet.
3. Opioid consumption will be recorded using the Patient Controlled Analgesia device and included on the trial sheet for 3 days post op.

Key secondary outcome(s))
Not provided at time of registration

Completion date
01/05/2003

Eligibility

Key inclusion criteria
80 women aged 30 to 70 years undergoing elective gynaecological surgery performed through a transverse incision in the lower abdomen.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Patients with a known allergy to morphine, fentanyl, propofol, vecuronium, diclofenac or marcain.
2. Regular medication with opioids for the last 6 months.
3. Body mass index (BMI) greater or equal to 32.
4. Previous major surgery during the last 6 months.

Date of first enrolment
01/03/2002

Date of final enrolment
01/05/2003

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Heatherwood and Wexham Park Hospitals NHS Trust
Slough
United Kingdom
SL2 4HL

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Heatherwood and Wexham Park Hospitals NHS Trust (UK)

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	11/11/2025	No	Yes