

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 04/04/2016	Condition category Signs and Symptoms	<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

Contact name
Mr Philip Reginald

Contact details
Heatherwood and Wexham Park Hospitals NHS Trust
Department of Obstetrics & Gynaecology
Wexham Park Hospital
Slough
United Kingdom
SL2 4HL
+44 (0)1753 634509
philip.reginald@hwph-tr.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

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 marcaïn 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 measure

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.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/03/2002

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

Age group

Adult

Sex

Female

Target number of participants

80

Key exclusion criteria

1. Patients with a known allergy to morphine, fentanyl, propofol, vecuronium, diclofenac or marcaïn.
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

England

United Kingdom

Study participating centre

Heatherwood and Wexham Park Hospitals NHS Trust

Slough

United Kingdom

SL2 4HL

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Heatherwood and Wexham Park Hospitals NHS Trust (UK)

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