

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

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

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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 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(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 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**

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