

# Antiemetic efficacy of combination Cyclizine-Morphine patient controlled analgesia in postoperative major gynaecological surgery patients

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 31/03/2020	<b>Condition category</b> Surgery	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

## Secondary identifying numbers

N0128125461

# Study information

## Scientific Title

Antiemetic efficacy of combination Cyclizine-Morphine patient controlled analgesia in postoperative major gynaecological surgery patients

## Study objectives

To compare the efficacy of combination morphine plus cyclizine patient controlled analgesia (PCA) versus morphine alone in PCA in patients undergoing major gynaecological surgery following a single prophylactic intravenous dose of cyclizine in theatre. We aim to identify the dose of cyclizine per PCA bolus that is most effective against post-operative nausea and vomiting (PONV) but has minimal side effects.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Study design

Prospective randomised double blind controlled pilot study

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Not Specified

## Participant information sheet

## Health condition(s) or problem(s) studied

Surgery: Gynaecological

## Interventions

Compare the efficacy of combination morphine plus cyclizine patient controlled analgesia (PCA) versus morphine alone in PCA in patients undergoing major gynaecological surgery following a single prophylactic intravenous dose of cyclizine in theatre.

## Intervention Type

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Cyclizine, Morphine

**Primary outcome measure**

Assessment of nausea and vomiting, pain scores, morphine requirements, sedation, the need for rescue antiemetic medication, incidence of side effects

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

10/11/2003

**Completion date**

10/04/2004

**Eligibility****Key inclusion criteria**

90 subjects will be recruited in total, between 18-65 years old.

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

65 Years

**Sex**

Female

**Target number of participants**

90

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

10/11/2003

**Date of final enrolment**

10/04/2004

# Locations

## Countries of recruitment

England

United Kingdom

## Study participating centre

### Anaesthesia Department

Liverpool

United Kingdom

L8 7SS

# 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

Government

## Funder Name

Liverpool Women's Hospital 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