

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

Submission date 30/09/2004	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 30/09/2004	Overall study status Completed	☐ Protocol
Last Edited 31/03/2020	Condition category Surgery	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ 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

Protocol serial number

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

Study type(s)

Not Specified

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

Female

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

United Kingdom

England

Study participating centre

Anaesthesia Department

Liverpool

United Kingdom

L8 7SS

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

Liverpool Women's Hospital NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration