ISRCTN84471191 https://doi.org/10.1186/ISRCTN84471191

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

Registration date
30/09/2004

Overall study status
Completed

Last Edited
31/03/2020

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] 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

Contact name
Dr Philip Barclay

Contact details
Anaesthesia Department
Liverpool Women's Hospital
Crown Street
Liverpool
United Kingdom
L8 7SS
+44 (0)151 708 9988
abc@email.com

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