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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 [_] Protocol
Registration date 30/09/2004	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 31/03/2020	**Condition category** Surgery	[_] 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

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