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Prophylaxis against Postoperative Vomiting (PaPoV) study: a prospective, controlled randomised double-blind trial comparing antiemetic prophylaxis with ondansetron, cyclizine and placebo (normal saline) in children undergoing plastic genito-urinary (GU) procedures

Submission date
12/09/2003

Recruitment status
No longer recruiting

Registration date
12/09/2003

Overall study status
Completed

Last Edited
09/07/2009

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
N0557102800

Study information

Scientific Title

Acronym
PaPoV

Study objectives
To assess the incidence of postoperative vomiting in children undergoing genital plastic surgery in a prospective, randomised, double blind study comparing ondansetron with cyclizine and placebo (normal saline).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised double blind controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Signs and Symptoms: Vomiting

Interventions
Prospective, controlled randomised double-blind trial.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
ondansetron cyclizine

Primary outcome(s)
Number of vomits in the first 24 h from the time of extubation; doses of anti-emetics given because of vomiting in the first 24 h; time to first oral intake; complications (obtained retrospectively from case notes).

Key secondary outcome(s)

Not provided at time of registration

Completion date
30/09/2003

Eligibility

Key inclusion criteria
Children undergoing elective plastic genito-urinary procedures between the ages of 3 and 5, American Society of Anesthesiologists (ASA) grade I & II. 55 Children in each group.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Sex
Not Specified

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/01/1997

Date of final enrolment
30/09/2003

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Consultant Anaesthetist
Dudley
United Kingdom
DY1 2HQ

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The Dudley Group of Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2003		Yes	No