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Prevention of post-operative nausea and vomiting (PONV) in 'day surgery patients'; Granisetron v/s Placebo, Cyclizine and Ondansetron.

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/09/2005	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 11/04/2014	**Condition category** Signs and Symptoms	[_] 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
N0084144579

Study information

Scientific Title

Study objectives
To compare the effectiveness of granisetrone with ondansetrone, cyclizine and placebo in the prevention of post-operative nausea and vomiting in patients undergoing "Day Surgery" under general anaesthesia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Signs and Symptoms: Post operative nausea and vomiting (PONV)

Interventions
Patients are to continue to have general anaesthesia for their surgical procedure. Every participating patient to receive a prophylactic anti emetic, randomly selected, at the beginning of anaesthetic induction.

Anti emetics to be divided into 4 groups:
A: Cyclizine 50mgm I.V.
B: Ondansetrone 4mgm I.V.
C: Granisetrone 1mgm I.V
D: Placebo.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Post operative record of patients PONV status to be recorded by the nurse in PACU (Post anaesthetic care unit). Rescu anti-emetic to be given by the nurse in PACU as per protocol. Emesis score as follows: 0 - None; 1 - Nausea; 2 - Retching; 3 - Vomiting. Patient to complete the simple questionnaire regarding her post operative recovery and return by pre-paid envelope the next day.

Key secondary outcome(s)
Not provided at time of registration

Completion date
01/09/2004

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/09/2003

Date of final enrolment
01/09/2004

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Northern Lincolnshire & Goole Hospitals NHS Trust
Grimsby
United Kingdom
DN33 2BA

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
Northern Lincolnshire and Goole Hospitals NHS Trust (UK), NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration