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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design
Randomised controlled trial

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
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 measure
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.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2003

Completion date
01/09/2004

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
It is anticipated to recruit 4 groups of 30 patients each = total of 120 patients into this study.

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

England

United Kingdom

Study participating centre
Northern Lincolnshire & Goole Hospitals NHS Trust
Grimsby
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Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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Sponsor type
Government

Website
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Funder(s)

Funder type
Government

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

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