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

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

## Study design
Randomised controlled trial

## Primary study design
Interventional

## 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