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

Submission date	Recruitment status	Prospectively registered
30/09/2005	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
30/09/2005	Completed	Results
Last Edited	Condition category	Individual participant data
11/04/2014	Signs and Symptoms	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Bhaskar Tandon

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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
United Kingdom
DN33 2BA

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

http://www.dh.gov.uk/Home/fs/en

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 summaryNot provided at time of registration