

A randomised double blind study looking at combination granisetron and cyclizine anti-emetic therapy versus single use granisetron or cyclizine in day case gynaecological patients

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/01/2009	Condition category Surgery	<input type="checkbox"/> 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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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0224112482

Study information

Scientific Title

Study objectives

Is a combination of prophylactic granisetron and cyclizine more effective in the prevention of post-operative nausea and vomiting than use as single agents in day case gynaecological patients?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised double blind study

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

Surgery: Gynaecological

Interventions

Combination granisetron and cyclizine anti-emetic therapy versus single use granisetron or cyclizine

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome measure

To see if the combination anti-emetic regime reduces post-operative nausea and vomiting.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/06/2002

Completion date

01/06/2004

Eligibility

Key inclusion criteria

Patients over 18 years of age undergoing a day case gynaecological procedure.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

Added January 2009: 960

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/06/2002

Date of final enrolment

01/06/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Consultant Anaesthetist

Torquay
United Kingdom
TQ2 7AA

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

South Devon Healthcare NHS Trust (UK)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2006		Yes	No