ISRCTN75581229 https://doi.org/10.1186/ISRCTN75581229

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

Registration date
12/09/2003

Overall study status
Completed

Last Edited
06/01/2009

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Jane Montgomery

Contact details
Consultant Anaesthetist
Day Surgery Unit
Torbay Hospital
Lawes Bridge
Torquay
United Kingdom
TQ2 7AA
+44 (0)1803 654310

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0224112482

Study information

Scientific Title

Study objectives
Is a combination of prophylatic 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