

A study to establish the efficacy of dexamethasone used in combination with cyclizine in the prevention of post operative nausea and vomiting

Submission date 30/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 10/07/2008	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data

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

N0355092655

Study information

Scientific Title

Study objectives

To investigate whether cyclizine is more effective than placebo in preventing post operative nausea and vomiting. A secondary aim is to establish whether a combination of cyclizine and dexamethasone is more effective than cyclizine alone.

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)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Signs and Symptoms: Nausea and vomiting

Interventions

1. Cyclizine 50mgs per-operatively and rescue ondansatron (control)
2. Dexamethasone 8mgs and cyclizine 50 mgs per-operatively and rescue ondansatron prn (combination)
3. 0.9% saline (placebo).

Randomisation: closed envelope technique. Anaesthetic: Propofol induction, nitrous oxide, isoflurane maintenance, Fentanyl 2 mgs/kg, Diclofenac 75 mgs I.v unless contraindicated. Patient airway maintained as deemed appropriate by the anaesthetist (recorded). Patient paralysed. All patients to receive iv fluids prn per-operatively. Paracetamol and/or codeine for rescue analgesia .

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

dexamethasone, cyclizine

Primary outcome measure

Data and demographics recorded - age, time from LMP, smoking Hx, time from starvation, type of surgery, previous postoperative nausea and vomiting (PONV) , previous travel sickness, duration of anaesthesia, reversal used (Y/N), time to first oral intake, time to first mobilisation, time to first food, time to discharge. Vomiting (Y/N) or retching (Y/N) in recovery @ 1, 2, 3 & 4 hours, nausea (none/mild/moderate/severe) in recovery and @ 1, 2, 3 & 4 hour, pain score (non /mild/moderate/severe) in recovery and @ 1, 2, 3 & 4 hours, rescue anti emetic usage (ondansatran).

Secondary outcome measures

Not provided at time of registration

Overall study start date

12/02/2001

Completion date

03/12/2003

Eligibility**Key inclusion criteria**

Women over the age of 18 undergoing daycase gynaecological laparoscopy.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

150

Key exclusion criteria

1. Failure to consent
2. Under 18 years old

Date of first enrolment

12/02/2001

Date of final enrolment

03/12/2003

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Mid Essex Hospital Services NHS Trust (BH)

Chelmsford

United Kingdom

CM1 7ET

Sponsor information

Organisation

Department of Health

Sponsor details

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79 Whitehall

London

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SW1A 2NL

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Sponsor type

Government

Website

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

Funder(s)

Funder type

Government

Funder Name

Mid Essex Hospital Services NHS Trust (UK)

Funder Name

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	abstract presented at Anaesthetic Research Society in Liverpool, British Journal of Anaesthesia 93 (4): 618P ():	01/10/2004		No	No