ISRCTN18556628 https://doi.org/10.1186/ISRCTN18556628

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

Registration date
30/09/2005

Overall study status
Completed

Last Edited
10/07/2008

Condition category
Signs and Symptoms

[_] 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

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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 (ondansatron).

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
Richmond House
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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