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Prevention of POstoperative Nausea and Vomiting with metoclopramide and dexamethasone

Submission date	Recruitment status	[ ] Prospectively registered
07/09/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
17/10/2005	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/02/2008	Signs and Symptoms	

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
N/A

Study information

Scientific Title

Acronym
MultiPONV

Study objectives
A prophylactic treatment of postoperative nausea and vomiting consisting of an optimal dosage of metoclopramide combined with dexamethasone increases effectiveness and lowers side effects.

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)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Postoperative nausea and/or vomiting following inhalational or regional anaesthesia.

Interventions
The patients were randomised to receive either of 0, 10, 25 or 50 mg metoclopramide in addition to 8 mg dexamethasone.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Metoclopramide, dexamethasone

Primary outcome measure
Occurrence of nausea and/or vomiting within 24 hours after the end of surgery.

Secondary outcome measures
1. Occurrence of post-operative nausea (PON) and vomiting (POV) separately
2. Frequency and severity of PON and POV
3. Time to first PONV event
4. Need of rescue medication
5. Frequency of hypotension and arrhythmia after intra-operative administration of the study drugs
6. Frequency and severity of adverse effects within 24 hours after the end of surgery:
6.1. Headache
6.2. Dizziness
6.3. Drowsiness
6.4. Dry mouth
6.5. Itching
6.6. Flush
6.7. Urticaria
6.8. Restlessness
6.9. Extrapyramidal symptoms
6.10. Dyskinesia
6.11. Central-anticholinergic syndrome
6.12. Bradycardia/tachycardia

Overall study start date
12/01/2004

Completion date
14/12/2004

Eligibility

Key inclusion criteria
1. Age greater than 18 years
2. Patient receives balanced anaesthesia (with intubation) or spinal, peridural, or combined spinal epidural anaesthesia for any of the following surgeries:
2.1. Hysterectomy
2.2. Cholecystectomy
2.3. Hernia repair
2.4. Otorhinolaryngological surgery
2.5. Thyroid surgery
2.6. Total endoprothesis of the hip or knee
2.7. Arthroscopy
3. Patient is able to answer questions regarding symptoms (taking his/her physical, emotional and mental constitution, understanding and compliance into consideration)
4. Informed consent in writing

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
3000

Key exclusion criteria
1. Anaesthesiological risk level of American Society of Anaesthesiologists (ASA) IV
2. Presence of at least one of the following cardiac risk factors:
2.1. Unstable angina pectoris
2.2. Heart failure with New York Heart Association (NYHA) greater than or equal to III and/or left ventricular ejection fraction (LVEF) less than 40%
2.3. Atrioventricular block grade II or III
3. Current treatment with any of the following:
3.1. Study medication
3.2. Other anti-emetic drugs except ranitidine
3.3. Selective serotonin reuptake inhibitors (SSRIs)
3.4. Monoamine oxidase (MAO) inhibitors
3.5. Tricyclic antidepressants
3.6. Antiarrhythmics class I or III
4. Disposition of the patient to malignant hyperthermia, or known occurrence thereof
5. History of any of the following diseases:
5.1. Parkinson's disease and other extrapyramidal-motoric impairment
5.2. Hepatic insufficiency (alanine aminotransferase [ALT] and/or aspartate aminotransferase [AST] greater than 2 x upper normal value [UNV])
5.3. Renal insufficiency (Creatinine greater than 2 x UNV)
5.4. Phaeochromocytoma
5.5. Mechanical ileus
5.6. Epilepsy
6. Known anaphylaxis following any of the study drugs
7. Pregnancy or breast feeding
8. Participation in another therapeutic trial
9. Planned or foreseeable post-operative application of propofol
10. Planned or foreseeable post-operative artificial respiration
11. Planned or foreseeable leaving of a stomach tube post-operatively

Date of first enrolment
12/01/2004

Date of final enrolment
14/12/2004

Locations

Countries of recruitment
Germany

Study participating centre
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Sponsor information

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University of Leipzig (Germany)

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Sponsor type
University/education

ROR
https://ror.org/03s7gtk40

Funder(s)

Funder type
University/education

Funder Name
Self-funded by the Department of Anaesthesiology and Intensive Care Medicine and by the Committee of Clinical Innovation of the University of Leipzig (Germany).

Funder Name
Supply of the study drugs free of charge by the manufacturers.

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	12/08/2006		Yes	No