

Prevention of POstoperative Nausea and Vomiting with metoclopramide and dexamethasone

Submission date 07/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 17/10/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/02/2008	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

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

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. Extrapyrimal symptoms
- 6.10. Dyskinesia
- 6.11. Central-anticholinergic syndrome
- 6.12. Bradycardia/tachycardia

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 endoprosthesis 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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. Pheochromocytoma
 - 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

Liebigstr. 20

Leipzig

Germany

D-04103

Sponsor information

Organisation

University of Leipzig (Germany)

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

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