ISRCTN31625370 https://doi.org/10.1186/ISRCTN31625370

# 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
**Liebigstr. 20**
Leipzig
Germany
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## Sponsor information

### Organisation
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 |