Effect of droperidol 2,5 mg added to 100 mg morfine in PCA therapy in combination with ondansetron and dexamethasone against PONV.

Published: 14-12-2007
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The aim of the study is to investigate the surplus value of droperidol on top of het combination ondansetron and dexamethasone.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Interventional

Summary

ID

NL-OMON31800

Source
ToetsingOnline

Brief title
DROPPOMB

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
postoperative nausea and vomiting

Research involving
Human

Sponsors and support

Primary sponsor: Amphia Ziekenhuis
Source(s) of monetary or material Support: eigen middelen

Intervention

Keyword: dexamethasone, Droperidol, ondansetrone, PONV

Outcome measures

Primary outcome

Primary endpoint is PONV yes or no. PONV is defines as at least one time vomited of nausea (verbal rating scale 2 or more) within 24 hours postoperative.

Secondary outcome

Secondary endpoints are PONV after 48 and 72 hours postoperative, number of times vomited, consumption of morfine, metoclopramide and ondansetron after 24, 48 and 72 hours postoperative and number of patients who develop delirium 72 hours postoperative.

Study description

Background summary

Postoperative nausea and vomiting (PONV) are the most common complaints after anesthesia and surgery. Patients perceive PONV as one of the most bothersome anesthesia related adverse effects and can be reason for longer hospitalstay. Good profylaxis can reduce PONV. The CBO guidelines advise combination therapy with ondansetron and dexamethason. In spite of the profylaxis there are still patients with PONV.

Study objective

The aim of the study is to investigate the surplus value of droperidol on top of het combination ondansetron and dexamethasone.

Study design

It's a double-blind placebo-controlled randomized study.
Postoperative patients receive a PCA pump with 50 ml morfine 5 mg/ml.

Patients in the droperidolgroup receive 2,5 mg droperidol, once added to the morfine. In the placebo group there's no addition to the morfine.
Further antiemetic treatment is according to standard procedure.

Intervention

not applicable

Study burden and risks

not applicable

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

18 years and older
postoperative analgesia by means of a PCA pump with morfine

Exclusion criteria

Pregnancy, breastfeeding, serious depression, bradycardia (<55/min), hypopotassemia, pheochromocytoma, dopamin agonist use, prolonged QT-interval, alcoholism

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-06-2008
Enrollment:	120
Type:	Actual

Medical products/devices used

Product type:	Medicine
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	14-12-2007
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-05-2008
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2007-004914-16-NL
CCMO	NL19560.101.07