Prevention of constipation during treatment with opioids: magnesiumoxide versus macrogol/elektrolytes

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The aim of the study is to compare magnesiumhydroxide and polyethylene glycol/electrolytes with regard to the prevention of constipation and side-effects in palliative care cancer patients starting with opioids.

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

Summary

ID

NL-OMON33671

Source
ToetsingOnline

Brief title
ConstipationOpioids

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
Constipation/difficulty with bowel movements

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Constipation, Magnesiumhydroxide, Opioids, Polyethylene glycol/Elektrolytes

Outcome measures

Primary outcome

Primary endpoint:

Degree of constipation as defined by the total score of the Patient Assessment of Constipation-Symptom (PAC SYM;constipation symptom assessment instrument) after 2 weeks of treatment.

The PAC SYM is an instrument to measure the degree and symptoms of constipation during the previous week. It contains 12 items scored by the patient on a 5-point Likert scale. The scores can be calculated en give insight in 3 domains: symptoms of defaecation, rectal symptoms and abdominal symptoms. The instrument has been validated for patients with chronic functional constipation and for patients using opioids for chronic back pain. In the last study a Dutch version has been used.

Secondary outcome

Secundary endpoints:

· Degree of contipation:

Totalscore PAC-SYM after 4, 6 and 8 weeks

Scores of subscales of the PAC-SYM after 2, 4, 6 and 8 weeks

Presence of Rome III criteria for constipation (2, 4, 6 and 8 weeks)

· Consequences of constipation for daily activities and functioning (2, 4, 6 and 8 weeks)

· Side-effects of laxatives(2, 4, 6 and 8 weeks)

· Patient preference (8 weeks)

Meetinstrumenten

. PAC-SYM (see above)

· Presence of Rome III criteria for constipation :

straining at least 25% of the time

incomplete evalcuation at least 25% of the time

feeling of rectal obstruction at least 25% of the time

necessity for manual manoeuvres to facilitatie defaecation at least

25% of the time

less than 3 bowel movements per week

Constipation is present if two or more criteria are met

· Consequences of constipation for daily activities and functioning (numeric

scale 0-10)

To what degree does constipation has influence on your daily life?

To whatr degree does constipation has influence on your quality of

life?

· Side effects of laxatives:

To what degree did you find taking laxatives easy (numeric scale

0-10)?

To what degree did you find the taste of the laxatives unpleasant

(numeric scale 0-10)?

Have you experienced side effects of the polyetylene

glycol/electrolytes or the magnesiumhydroxide? If so, which side-effects?

Patient preference (after using both laxatives): do you

prefer one of the laxatives over the other?

Study description

Background summary

Constipation occurs in 36-42% of palliative care cancer patients. Constipation is the passage of hard faeces infrequently and with difficulty. The consequences of constipation vary from discomfort for the patient to bowel obstruction. Adequate prevention and treatment is essential. However, the efficacy and side-effects of laxatives have been poorly studied and a choice, based on scientific evidence cannot be made.
One of the most frequent causes of constipation in palliative care patients is opioid use. Therefore, laxatives are routinely prescribed when starting opioids. A Dutch national guideline on constipation recommends either polyethylene glycol/electrolytes or magnesium hydroxide. A definite choice between these two laxatives cannot be made because of lack of clinical studies.

Study objective

The aim of the study is to compare magnesiumhydroxide and polyethylene glycol/electrolytes with regard to the prevention of constipation and side-effects in palliative care cancer patients starting with opioids.

Study design

This is a randomized, open label study with cross-over
Patients are randomized between:
- 4 weeks of treatment with magnesiumhydroxide, followed by 4 weeks of polyethylene glycol/electrolytes
- 4 weeks of polyethylene glycol/electrolytes followed by 4 weeks of treatment with magnesiumhydroxide
Thus, the duration of the study is 8 weeks

Intervention

Interventions (cross-over after 4 weeks):
1. Magnesiumhydroxide (3dd 724 mg orally) or magnesiumoxide (3dd 500 mg orally) during 4 weeks; if there is no effect (defined as 3 days without bowel movements or passage of hard faeces during 3 days) the dose is doubled. If there is no effect of the double dose add bisacody 5 mg a.n.
2. Polyethylene glycol/electrolytes 13.1 g orally; during 4 weeks; if tehre is

no effect (defined as 3 days without bowel movements or passage of hard faeces during 3 days) the dose is doubled. If there is no effect of the double dose add bisacody 5 mg a.n.

Study burden and risks

The patients use magnesiumhydroxide and polyethylene glycol/electrolytes each for 4 weeks. Side effects may include bloating, flatulence, abdominal pain, unpleasant taste, nausea, vomiting and diarrhoea. Patients using magnesiumhydroxide are at risk for hypermagnesemia.
If the patients would be treated outside the study protocol, a laxative (usually magnesiumhydroxide, polyethylene glycol/electrolytes or lactulose) would also be prescribed.
The patients have to complete the questionnaires five times within 8 weeks. It is estimated that this will take 20 minutes each time.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

Palliative care cancer patients starting with opioids
Age >18 years

Exclusion criteria

Contra-indication for laxative use
Use of laxatives up to 4 weeks before entry in the study
Serum creatinine >180 ug/l
Estimated life expectancy <3 months

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-01-2010
Enrollment:	155
Type:	Actual

Medical products/devices used

Product type:	Medicine

Brand name:	-
Generic name:	Magnesium hydroxide
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	?
Generic name:	Polyethylene glycol/electrolytes
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	06-11-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	13-01-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	EUCTR2007-007610-10-NL
CCMO	NL24626.041.08