A randomized double-blind placebo controlled trial to evaluate the value of a single bolus intravenous alfentanil in CT-colonography

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Primary Objective: To evaluate whether a single intravenous alfentanil bolus (7.5 mcg/kg) has a clinically significant analgesic effect in clinical patients who undergo an elective CT-colonography compared to placebo. We have defined a clinically...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Benign neoplasms gastrointestinal
Study type	Interventional

Summary

ID

NL-OMON35816

Source
ToetsingOnline

Brief title
Alfentanil in CT-colonography

Condition

- Benign neoplasms gastrointestinal
- Gastrointestinal neoplasms malignant and unspecified

Synonym
colorectal cancer, large bowel cancer

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Alfentanil, Analgesia, CT-colonography, Placebo

Outcome measures

Primary outcome

The difference between the alfentanil group and placebo group in maximum pain score during insufflation.

Secondary outcome

Differences in:

*Pain score in all insufflation positions (left and right decubitus, supine and prone) and the average pain score

*Pain and burden of all CT-colonography aspects (telebrix, cannula insertion, insufflation) and total pain and burden of CT-colonography

*Side-effects of alfentanil during CT-colonography including:

- respiratory effects (apnoea, respiratory frequency and blood oxygenation)

- hemodynamics (heart rate and blood pressure)

*Procedure and recovery time

*The most painful and most burdenful aspect of CT-colonography

Study description

Background summary

Pain during CT-colonography is common. Apart from the discomfort and anxiety

during the procedure for symptomatic patients, this influences the adherence of CT-colonography as a possible screening tool for colorectal cancer. A short acting opioid as used in colonoscopy, such as alfentanil, will reduce pain and burden and thereby increase acceptance of CT-colonography. We hypothesize that alfentanil will reduce maximum pain by at least 1.3 point on a 11-point numeric rating scale scale and increase the acceptance of CT-colonography. (see for more background the protocol page 9)

Study objective

Primary Objective: To evaluate whether a single intravenous alfentanil bolus (7.5 mcg/kg) has a clinically significant analgesic effect in clinical patients who undergo an elective CT-colonography compared to placebo. We have defined a clinically significant effect as a pain reduction of 1.3 point on an 11-point numeric rating scale.

Secondary Objectives:
To assess differences in:
*Pain score in all insufflation positions (right and left decubitus, supine and prone) and the average pain score
*Pain and burden of all CT-colonography aspects (Telebrix, cannula insertion, insufflation) and total pain and burden of CT-colonography
*Side-effects of alfentanil during CT-colonography including:
- respiratory effects (apnoea, respiratory frequency and blood oxygenation)
- hemodynamics (heart rate and blood pressure)
*Procedure and recovery time
*The most painful and most burdenful aspect of CT-colonography

Study design

Prospective double-blind randomized placebo controlled trial.

Intervention

Two questionnaires with approximately 15 multiple-choice questions shall be given during
this study: the first before randomization and the second after completion of the CT-colonography procedure (appendix 1 and 2).
Oxygen saturation, heart rate and blood pressure will be measured during the CT-colonography procedure, using a pulse oxymeter and automated blood pressure monitor.
The participants randomized to group 1 will receive alfentanil (Rapifen; Janssen-Cilag, Tilburg, The Netherlands) 7.5 mcg/kg intravenously through the cannula. The participants from group 2 will receive a placebo, in this study a 0.9% saline solution. This placebo is chosen because alfentanil is dissolved in

0,9% saline solution. Both the physician performing the CT-colonography scan as well as the patient are blinded to the allocated group.

Study burden and risks

- Two questionnaires with approximately 15 multiple-choice questions
- Monitoring oxygen saturation and blood pressure during the procedure, using a pulsoximeter and automated blood pressure monitor. And asking the patient 4 times for a pain score during the insufflation.
- The need for an intravenous cannula in the arm, which is not always necessary in routine clinical practise (although always intra venous medication is administrated during CT-colonography).
- Adverse events, such as: respiratory depression, apnoea, transient hypotension, bradycardia, dizziness, nausea and vomiting (only for the participants randomized to group 1 may experience side-effects of alfentanil) The risk of serious adverse events is very small with the low dose alfentanil used in this study. For example in a study of Usta et al. a combination of a benzodiazepine and alfentanil low dose even did not cause any serious adverse events. (see chapter 6.5 of the protocol, page 17)
- Approximately 45 minutes extra time for observation/monitoring after the procedure.

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

18 tot 85 years
Written informed consent
Scheduled for CT-colonography for symptoms or increased risk for colorectal cancer (including patients referred after incomplete colonoscopy)

Exclusion criteria

Hypotension (systolic blood pressure <90mmHg)
Bradycardia (heart rate < 50 bpm)
Severe COPD
Known allergy for alfentanil
Pregnancy
Severe liver disease (defined as a Child-Pugh score >4)
Use of MAO-inhibitors or within two weeks before the CT-colonography procedure
Use of barbiturates, opiates or daily benzodiazepine use
Known increased intracranial pressure

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2011
Enrollment:	90
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Rapifen
Generic name:	Alfentanil
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Sodiumchloride 0,9%
Generic name:	Sodiumchloride 0,9%
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	03-03-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-12-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	EUCTR2011-000970-78-NL
CCMO	NL35916.018.11