Alfentanil in CT-colonography.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25320

Source
NTR

Health condition

Pain
Ct-colonography
Colorectal cancer
Polyps

Sponsors and support

Primary sponsor: Academic Medical Center
Source(s) of monetary or material Support: Academic Medical Center

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

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

2. Pain and burden of all CT-colonography aspects (telebrix, cannula insertion, rectal catheter insertion, insufflation, turing on scanner table, post-procedure) and total pain and burden of CT-colonography;

3. Side-effects of alfentanil during CT-colonography including:

A. Respiratory effects (apnoea, respiratory frequency and blood oxygenation);

B. Hemodynamics (heart rate and blood pressure).

4. Procedure and recovery time;

5. The most painful and most burdenful aspect of CT-colonography.

Study description

Background summary

Background/Hypothesis:

Although CT-colonography is a less invasive alternative for colonoscopy for the detection of colorectal polyps and cancer, procedural pain is common. In several studies CT-colonography pain and burden is higher than in colonoscopy. Apart from the discomfort and anxiety during the procedure, this may influence the adherence for CT-colonography as a possible screening tool for colorectal cancer. We hypothesize that a single bolus intravenous alfentanil will give a clinically significant reduction in maximum pain defined as at least 1.3 point reduction on an 11-point numeric rating scale (NRS).

Design:

Single-centre randomised double-blind placebo controlled trial.

Methods:

Patients scheduled for an elective CT-colonography in a single tertiary centre are eligible for inclusion. The first 90 consenting patient will be block-randomized in either the alfentanil group or the placebo group. Before bowel insufflation, the alfentanil group receives a single bolus intravenous alfentanil 7.5ìg/kg dissolved in 0.9% NaCL while the placebo group receives an intravenous bolus injection of pure 0.9% NaCl. For both groups an equal amount of fluid per kilogram (75ìl/kg) is injected. The primary outcome is the difference in maximum pain on

an 11-point NRS. Secondary outcomes include: pain and burden of different CT-colonography aspects, side effects, procedural time and recovery time. For the primary outcome a T-test or Wilcoxon-Ranksum test is performed depending on the distribution with a p-value < 0.05 is considered statistically significant.

Study objective

We hypothesize that alfentanil will reduce maximum pain score by at least 1.3 point on a 11-point numeric rating scale.

Study design

Before inclusion the patients sceduled for CT-colonography are contacted by telephone. Questions regarding the inclusion and exclusions are asked and recorded.

Before the CT-colonography examination a pre-procedure questionnaire is filled in by all participants. This questionnaire contains 22 questions mostly concerning the pain and burden expectations of different CT-colonography aspects (preparation, cannula insertion, rectal catheter insertion, insufflation, turning on the scanner table, post-procedure).

During the procedure the oxygen saturation and bloodpressure is monitored. At the end of all insufflation positions during CT-colonography, a pain score is asked on a 11-point numeric rating scale. Side-effects and begin and end time are recorded.

After the procedure the Aldrete score is used to assess the recovery. this score is assessed at directly after the procedure and at 30 and 60 minutes after the alfentanil or placebo injection.

30 minutes after the procedure a post-procedure questionnnaire is given to all participants. This questionnaire contains 17 questions concerning the experienced pain and burden of different CT-colonography aspects (same as in pre-procedure questionnaire).

Intervention

Subjects randomised to group 1 will receive alfentanil (Rapifen; Janssen-Cilag, Tilburg, The Netherlands) 7.5 ìg/kg intravenously through a 20 Gauge intravenous cannula. Subjects randomised to group 2 will receive a placebo, in this study a 0.9% saline solution through a 20 Gauge intravenous cannula. For both groups an equal amount of fluid (75ìl/kg) will be

injected. This placebo is chosen because alfentanil is dissolved in 0.9% saline solution. After administration of the spasmolytic agent the line is flushed with 10 ml 0.9% and again after administration of the study medication. Both the physician performing the CT-colonography scans as well as the patient are blinded to the allocated group.

Oxygen saturation, heart rate and blood pressure will be measured during the CT-colonography procedure, using a pulse oximeter and automated blood pressure monitor. A pain inventory will be performed insufflation in left decubitus, right decubitus, supine and prone position (see section pain inventory). Two questionnaires with 22 and 17 questions, mostly multiple-choice, shall be given during this study: the first before randomization and the second after completion of the CT-colonography procedure.

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Eligibility criteria

Inclusion criteria

1. 18 to 85 years;

2. Written informed consent;

3. Sceduled for CT-colonography for symptoms or increased risk for colorectal cancer.

Exclusion criteria

1. Hypotension (systolic pressure <90mmHg);

2. Bradycardia (heart rate < 50 bpm);

3. Severe COPD;

4. Known allergy for alfentanil;

5. Pregnancy;

6. Severe liver disease (Child-Pugh >4);

7. Use of MAO inhibitor or in 2 weeks before CT-colonography;

7. Use of barbiturates, opiates or daily benzodiazepine use;

8. Known increased intracranial pressure.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-05-2011
Enrollment:	90
Type:	Actual

Ethics review

Positive opinion

Date:	17-05-2011
Application type:	First submission

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
NTR-new	NL2763
NTR-old	NTR2902
Other	METC / EudraCT / Sponsor : 2011_066 / 2011-000970-78 / 2011-001;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A