

# Alfentanil in CT-colonography.

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

<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving gestopt
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON25320

### Bron

NTR

### Aandoening

Pain  
Ct-colonography  
Colorectal cancer  
Polyps

### Ondersteuning

**Primaire sponsor:** Academic Medical Center  
**Overige ondersteuning:** Academic Medical Center

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

#### Primaire uitkomstmaten

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

# Toelichting onderzoek

## Achtergrond van het onderzoek

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 7.5µg/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 (75ml/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.

## Doel van het onderzoek

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

## Onderzoeksopzet

Before inclusion the patients scheduled 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 questionnaire 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).

### **Onderzoeksproduct en/of interventie**

Subjects randomised to group 1 will receive alfentanil (Rapifen; Janssen-Cilag, Tilburg, The Netherlands) 7.5 µg/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 (75µl/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.

## Contactpersonen

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### Wetenschappelijk

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. 18 to 85 years;
2. Written informed consent;
3. Scheduled for CT-colonography for symptoms or increased risk for colorectal cancer.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

## Onderzoeksopzet

### Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

### Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	19-05-2011
Aantal proefpersonen:	90
Type:	Werkelijke startdatum

## Ethische beoordeling

Positief advies	
Datum:	17-05-2011
Soort:	Eerste indiening

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

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

## Resultaten

### Samenvatting resultaten

N/A