

# The use of bowel relaxant Buscopan® to improve the detection of colonic polyps during colonoscopy

<b>Submission date</b> 03/11/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 17/11/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 22/03/2019	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

### Secondary identifying numbers

BUSCOPAN\_PDR1

# Study information

## Scientific Title

The influence of hyoscine N-butylbromide on the colonoscopic polyp detection: A prospective, double blind, randomised, placebo-controlled trial

## Study objectives

To investigate whether the administration of Buscopan® will improve the detection, removal and harvesting of colonic polyps during colonoscopy.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Submission to the Medical Ethics Committee at Isala Klinieken, Zwolle, The Netherlands expected by the end of November 2010

## Study design

Prospective double blind randomised placebo controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Screening

## Participant information sheet

1. Patient information form  
2. Insurance coverage explanation  
3. Contact addresses of investigator and independent consultant  
4. Signature form

## Health condition(s) or problem(s) studied

Colonoscopy; Colonic polyp; Colorectal carcinoma

## Interventions

Intravenous administration of Buscopan or 0.9% Natriumchloride Solutution (placebo) during colonoscopy.

No further interventions

The duration of the action of Buscopan is only 20 minutes, and in this time colonoscopy will be finished. Data on polyp removal etc will be recorded during colonoscopy. There will be no further follow up, but participants will be informed about the histology of removed polyps in the outpatient department, as per usual practice.

## Intervention Type

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Hyoscine N-butylbromide (Buscopan®)

**Primary outcome measure**

The number of colonoscopies during which at least one polyp has been found divided by the total number of colonoscopies

**Secondary outcome measures**

1. Polyp detection score

During each colonoscopy the number and shape of the polyps will be recorded.

Polyps < 5 mm will confer 3 points

Polyps 5-10 mm will confer 2 points

Polyps > 10 mm will confer 1 point

Scores will be made for flat / broad based polyps as well as rounded / pedunculated polyps.

2. Polyp removal ratio

The number of removed polyps divided by the number of detected polyps

3 Pathology retrieval ratio

The number of polyps send for pathological investigation divided by the number of removed polyps

4 Influence of age category

Categories are: 30 - 50 years, 51 - 70 years and > 70 years.

5 Influence of diverticulosis category

Categories are: 1: 0-2 diverticula, 2: 3-10 diverticula, 3: 11-20 diverticula en 4: > 20 diverticula.

6 Influence of the endoscopist

**Overall study start date**

15/01/2010

**Completion date**

15/01/2012

## **Eligibility**

**Key inclusion criteria**

1. Patients aged 30 years or older
2. Able to understand and give informed consent
3. Routinely referred for colonoscopy

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

672

**Key exclusion criteria**

1. Pregnancy
2. Myasthenia gravis
3. Exacerbation of inflammatory bowel disease
4. Suspicion of ongoing diverticulitis
5. Expectation of an estimated probability of complete colonoscopy of less than 50%, e.g. by the presence of a stenosis

**Date of first enrolment**

15/01/2010

**Date of final enrolment**

15/01/2012

**Locations****Countries of recruitment**

Netherlands

**Study participating centre**

Department of Gastroenterology and Hepatology

Deventer

Netherlands

7416 SE

**Sponsor information****Organisation**

Deventer Hospital (Netherlands)

**Sponsor details**

Nico Bolkesteinlaan 75

Deventer

Netherlands

7416 SE  
+31 (0)570 535147  
Borgtf@dz.nl

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.dz.nl>

**ROR**

<https://ror.org/05w8df681>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Deventer Hospital (Netherlands)

## **Results and Publications**

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/04/2012		Yes	No