ISRCTN25405865 https://doi.org/10.1186/ISRCTN25405865

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

Submission date 03/11/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/11/2010	**Overall study status** Completed	
Last Edited 22/03/2019	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 form2. Insurance coverage explanation3. Contact addresses of investigator and independent consultant4. 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 endocopist

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
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7416 SE

Sponsor information

Organisation
Deventer Hospital (Netherlands)

Sponsor details
Nico Bolkesteinlaan 75
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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?
Results article	results	01/04/2012		Yes	No