

The influence of hyoscine N-butylbromide on colonoscopic polyp detection ratio

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To investigate whether bowel relaxation, induced by administration of hyoscine N-butylbromide, improves the detection, removal and collection of colonic polyps during colonoscopy

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Benign neoplasms gastrointestinal
Study type	Observational non invasive

Summary

ID

NL-OMON36608

Source

ToetsingOnline

Brief title

Hyoscine N-butylbromide and colonic polyp detection

Condition

- Benign neoplasms gastrointestinal
- Gastrointestinal neoplasms benign

Synonym

Colonic Polyps, large bowel polyps

Research involving

Human

Sponsors and support

Primary sponsor: Deventer Ziekenhuis

Source(s) of monetary or material Support: Het onderzoek wordt door het Deventer Ziekenhuis zelf gefinancierd

Intervention

Keyword: Colonoscopy, Colorectal carcinoma prevention, Hyoscine N-butylbromide, Polyp detection

Outcome measures

Primary outcome

Poly detection ratio: the percentage of colonoscopies with at least one colonic polyp as compared to the total number of colonoscopies.

(Ref: colonoscopic Withdrawal Times and Adenoma Detection during Screening Colonoscopy. Barclay RL, Vicari JJ, Doughty AS, Johanson JF, Greenlaw RL. NEJM 2006;355 2533-2541)

Secondary outcome

- 1 The total number of polyps seen during colonoscopy, divided by the total number of colonoscopies
2. The total number of polyps removed during colonoscopy, divided by the total number of colonoscopies
3. The total number of polyps retrieved for pathological investigation, divided by the total number of colonoscopies

These parameters will be expressed in a percentage and will be determined for polyps with a stalk and for flat polyps, according to their respective sizes (< 5 mm, 5-10 mm, > 10 mm).

(Ref: Colonoscopic Withdrawal Times and Adenoma Detection during Screening Colonoscopy. Barclay RL, Vicari JJ, Doughty AS, Johanson JF, Greenlaw RL. NEJM 2006; 355:: 2533-2541)

Study description

Background summary

Colorectal carcinoma is an important problem and cause of death. A large proportion of cases can be prevented by the removal of the precursor lesions which is a colonic polyp. This is done via a colonoscopy, allowing for visual detection, removal and harvesting of polyps.

The problem is, that during colonoscopy up to 10% of polyps can be missed. Also, some patients present with colorectal cancer despite a negative colonoscopy in the preceding three years. It is generally assumed that these tumours have arisen from missed polyps.

This has instigated a lot of research on methods to improve polyp detection during colonoscopy.

The problem is that the colon is no smooth tube but has a lot of folds and bends. Some polyps may be hidden behind these folds.

Folds are caused by contractions of the circular muscle layer of the bowel.

There are indications that relaxation of the muscular layer will decrease the folds, and therefore may facilitate visual inspection. Currently, there is only

one underpowered study indicating that this indeed may be the case ($p=0,06$)

Polyps should not only be removed but also collected for pathology. This may be hampered by active peristalsis. It is unknown whether relaxation of the bowel will facilitate the collection of polyps.

Study objective

To investigate whether bowel relaxation, induced by administration of hyoscine N-butylbromide, improves the detection, removal and collection of colonic polyps during colonoscopy

Study design

prospective randomized placebo-controlled trial, double-blind

Study burden and risks

Participation bears burden nor risk. Participation is of unclear benefit

Contacts

Public

Deventer Ziekenhuis

Nico Bolkesteinlaan 75
7416 SE Deventer
NL
Scientific
Deventer Ziekenhuis

Nico Bolkesteinlaan 75
7416 SE Deventer
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

1. Patiënt is routinely referred for colonoscopy by GP or specialist, and the correct indication as well possible contraindications for the procedure have been verified by a gastroenterologist, which is a standard procedure in the Deventer Hospital
2. Patiënt is able to understand and give informed consent
3. The age should be above 30.

Exclusion criteria

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

Study design

Design

Study type:	Observational non invasive
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):	21-01-2011
Enrollment:	672
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Buscopan
Generic name:	Hyoscine N-Butylbromide
Registration:	Yes - NL intended use

Ethics review

Approved WMO	
Date:	10-12-2010
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO	
Date:	18-01-2011
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	EUCTR2010-023643-15-NL
ISRCTN	ISRCTN25405865
CCMO	NL34514.075.10