# Modified bowel preparation with ClearPath system* Colonoscopy A feasibility study

Published: 13-05-2011
Last updated: 04-05-2024

The primary aim of this feasibility study is to determine the quality of bowel cleansing in patients undergoing colonoscopy with the ClearPath system after modified bowel preparation.

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Gastrointestinal conditions NEC |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON36513

**Source**
ToetsingOnline

**Brief title**
Modified bowel preparation with ClearPath system* Colonoscopy

### Condition

- Gastrointestinal conditions NEC

**Synonym**
advanced colonic neoplasia (colorectal cancer and colonic polyps), colorectal disease

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Bowel preparation, Colonoscopy

## Outcome measures

### Primary outcome

The Ottawa bowel preparation quality scale during introduction and withdrawing

of the colonoscope.

### Secondary outcome

A. Patients tolerance and compliance:

• Acceptability of colon preparation

• Bowel preparation completion rate

• Satisfaction

• Symptoms

• Preferences

B. Colonoscopy results:

• Colonic polyp detection rate

• Other significant findings during colonoscopy

• Successful intubation of the cecum

• Total procedural time

• Total withdrawal time

• Second colonoscopy (or alternative investigating of the colon for example

CT-colonography) indicated?

# Study description

### Background summary

Polyethyleenglycol (PEG) is a non-absorbable, balanced electrolyte solution and in many clinics including the UMCU the recommended choice of bowel preparation. PEG does not cause volume shifts or disturbances in serum electrolytes compared to osmotic or saline laxatives (such as mannitol and NaP) which is especially important in elderly patients or patients with renal or cardiac disorders. An important disadvantage of PEG solutions is the amount and taste which compromises patients* tolerance. A recent meta-analysis reports an excellent or good quality of preparation in only 77% (34-98%) of the patients receiving PEG. Approximately 90% of the patients complete the recommended 4L of PEG. More than one third of the patients receiving PEG experience symptoms of nausea/vomiting, pain, discomfort or distention.

Poor compliance to bowel preparation instructions is one of the major risk factors for inadequate bowel preparation. Inadequate bowel cleansing has several consequences including a lower colonic neoplasm detection rate, increased complication risk, second colonoscopy and increased procedural time.

To further improve bowel cleansing without lowering patients* tolerance the ClearPath* Irrigation and Evacuation System (ClearPath system) has been developed by EasyGlide (Easy-Glide, Ltd., Kefar Truman, Israel). The ClearPath system is a disposable device which can be attached to the distal end of the colonoscope and has two channels, one for irrigation and one for evacuation, which can operate simultaneously. More powerful irrigation and suction with a larger tube can increase bowel cleansing during colonoscopy and therefore can improve visualization of the colon mucosa. Furthermore the working channel is constantly available which can improve visualization during procedures such as polypectomy. This feasability study will provide clinical experience and information about the effectiveness of this new system.

### Study objective

The primary aim of this feasibility study is to determine the quality of bowel cleansing in patients undergoing colonoscopy with the ClearPath system after modified bowel preparation.

### Study design

This feasibility study is a single-center study.

**Intervention**

Modified bowel preparation (2 liter PEG solution compared to the standard 4 liter PEG solution) prior to colonoscopy with the ClearPath* Irrigation and Evacuation System.

**Study burden and risks**

"All participants will be exposed to all regular risks of colonoscopy, i.e., bleeding, perforation and post-polypectomy syndrome. The study protocol differs in two major ways from standard colonoscopy:

1. Modified bowel preparation (2 instead of 4LColofort) may result in inadequate bowel cleansing. The ClearPath system however is able to remove remaining stool more adequately by more powerful suction and irrigation.

2. The ClearPath system is a new device and not part of standard clinical practice. Although the ClearPath system increases the diameter of the colonoscope with 6mm, we expect expect the ClearPath system is unlikely to cause major harm, when handled with care and according to predetermined instructions. Although three experienced endoscopists will perform all colonoscopies, there will likely be a learning curve which may cause a slight increase in procedural time. Furthermore, the removal of remaining bowel contents due to modified bowel preparation may also increase procedural time."

The ClearPath system has the potential to be of great advantage in patients with inadequate bowel preparation. Furthermore a modified bowel preparation prior to colonoscopy is likely to improve patients* tolerance. We do not expect clinically significant differences in clinical outcomes. The ClearPath system has been certified by the FDA in 2010 and approved by the CE in 2009 for upper and lower endoscopy in humans. This feasability study will provide us with important information for further studies with the ClearPath system.

# Contacts

**Public**
Universitair Medisch Centrum Utrecht

postbus 85500
3508 GA Utrecht
NL
**Scientific**
Universitair Medisch Centrum Utrecht

postbus 85500
3508 GA Utrecht
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

• Adults of 18 years or older
• Elective outpatient colonoscopy
• Diagnostic, screening or surveillance colonoscopy
• Written informed consent

## Exclusion criteria

• In hospital bowel preparation.
• Known colonic motility disorder e.g. hypothyroidism, chronic idiopathic intestinal pseudo-obstruction.
• Surveillance because of a family history of Lynch syndrome or previous history of inflammatory bowel disease (IBD).
• Scheduled intervention colonoscopy because of a lesion found during previous colonoscopy (for example polypectomy).
• Active IBD (including toxic megacolon).
• Known or suspected bowel disease with an increased risk of complications, for example diverticulitis.

# Study design

## Design

**Study type:** Interventional

| | |
|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 12-07-2011 |
| Enrollment: | 100 |
| Type: | Actual |

## Medical products/devices used

| | |
|---|---|
| Generic name: | ClearPath Irrigation and Evacuation System |
| Registration: | Yes - CE intended use |

# Ethics review

Approved WMO

| | |
|---|---|
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |

# 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 |
|---|---|
| CCMO | NL34767.041.10 |

# Study results

| | |
|---|---|
| Date completed: | 18-05-2012 |
| Actual enrolment: | 24 |