Evaluation of the Performance of the Motus Cleansing System (MCS)

Published: 01-08-2016
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To evaluate the performance of MCS in cleansing a poorly prepared colon.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal signs and symptoms
Study type	Interventional

Summary

ID

NL-OMON42655

Source
ToetsingOnline

Brief title
CL00016

Condition

- Gastrointestinal signs and symptoms

Synonym
Gastrointestinal signs, gastrointestinal symptoms

Research involving
Human

Sponsors and support

Primary sponsor: Motus GI Medical Technologies LTD
Source(s) of monetary or material Support: Study Sponsor Motus GI Medical Technologies LTD

Intervention

Keyword: Cleansing, Colonoscopy, Motus GI, Preparation

Outcome measures

Primary outcome

To evaluate the performance of MCS in cleansing a poorly prepared colon.

The rate of adequate cleansing level per subject will be evaluated by the BBPS

(The Boston Bowen preparation Scale) scoring index pre- and post the cleansing

operation.

Secondary outcome

To evaluate the safety related to the MCS. To this purpose, the type,

incidence, severity, and duration of adverse events will be assessed.

Study description

Background summary

Colonoscopy is an endoscopic examination of the colonic mucosa. The procedure is considered the *gold standard* for detecting, diagnosing and treating abnormalities in the colon and is widely used for various clinical indications. High-quality colonoscopy is imperative for enhancing efficacy of and for decreasing the costs associated with the procedure. A key factor for ensuring high quality colon visualization using colonoscopy is a good colon preparation. Despite the importance of good preparation, many patients do not or are not able to adequately prepare themselves prior to the colonoscopy procedure. It is estimated that as many as 33% of colonoscopy patients arrive for their colonoscopy with inadequate colon preparation1. Factors that contribute to poor preparation include inconvenience and discomfort of ingesting cleansing agents (laxatives), concerns about lost work days, contraindication to cleansing agents, obesity and immobility due to medical condition or old age. Achieving a good level of colon preparation is one of the major barriers to successful and cost effective colonoscopy for colorectal cancer screening as well as for diagnosis of other gastrointestinal conditions.
Motus Cleansing System (MCS) facilitates a thoroughly-cleansed bowel for subjects with a poorly prepared colon. By providing intra-procedural mechanical colon cleansing, the MCS reduces reliance on subject pre-procedure colon preparation for ensuring high quality colonoscopy. By offering simple, fast, safe and effective intra-procedural cleansing, the MCS is expected to improve

the quality of colonoscopy to reduce the need for repeat colonoscopies, to increase the patient compliance to colonoscopy procedure and to reduce the patient dependency on the quality of the procedure.

Study objective

To evaluate the performance of MCS in cleansing a poorly prepared colon.

Study design

Prospective, multi-center, single-arm, open-label study

Intervention

Use of Motus Cleansing System (MCS)to enable colon cleansing during standard colonoscopy using a standard colonoscope. The cleansing device, which is attached to the tip of the colonoscope and is connected to an external workstation, generates fluid jets within the colon thus dissolving the feces into small parts. The fecal matter & fluids are drained through the evacuation pipe of the cleansing device into a collecting reservoir.

Study burden and risks

The potential risks associated with the participation in the clinical investigation may include a repeated colonoscopy procedure as the subjects enrolled to the study are required to undergo a limited prep as compared to the preparation given prior to standard colonoscopy procedure to mimic a poor colon preparation.
Based on previous clinical data an excellent cleansing effectiveness was demonstrated following the use of the MCS device ; MCS improved the cleansing level from 30% at baseline to 93% after the cleansing was operated, where the preparation in these studies were identical to the preparation in current study, for further detailed please refer to the "clinical evaluation report" (see pages 5-8 of the Risk Benefit assessment document).
Therefore, it is expected that the risk of a repeated colonoscopy procedure is low.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Subjects being considered for diagnostic, screening or surveillance colonoscopy
2. Subjects in the age range of 18-75 years inclusive
3. Subjects with BodyMass Index (BMI) within the range of 18.5-35 inclusive
4. Subject has signed the informed consent

Exclusion criteria

1. Subjects with known Inflammatory Bowel Disease
2. Subjects with known diverticulitis disease or with prior incomplete colonoscopy due to diverticular disease
3. Subjects with known or detected (during colonoscopy) bowel obstruction
4. History of prior surgery to colon and/or rectum
5. ASA>=IV
6. Renal insufficiency (Creatinine >= 1.5mg /dL) (based on medical history)
7. Abnormal Liver enzymes (ALT/AST >= 2 times upper limits of normal) (based on medical history)
8. Subjects taking anticoagulants drugs or dual antiplatelet therapy
9. Subjects with known coagulation disorder (INR >1.5).
10. Subjects treated with H2 receptor antagonists or proton pump inhibitors within the 72

hours prior to consuming the Bisacodyl
11.Subjects with active, ongoing lower GI bleeding with hemodynamic instability.
12.Subjects with known Mega Colon
13 Pregnancy (as stated by patient) or breast feeding
14. Subjects with altered mental status/inability to provide informed consent
15. Patients who have participated in another interventional clinical study in the last 2 months

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):	20-12-2016
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	Motus Cleansing System
Registration:	No

Ethics review

Approved WMO Date:	01-08-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	12-12-2016

Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL54357.091.15