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Introduction:

During a standard colonoscopy, the folds within the colon can negatively impact the endoscope's view, reducing the ability to detect polyps. In order to help remedy this issue, there is a new provisional device called **ENDORINGS™** . This device is a short silicone rubber tube with flexible circular wings mounted on the tip of the colonoscope to facilitate endoscopic therapy. By flattening the colonic folds during withdrawal, this device could help to keep a suitable depth of the endoscope's view field and, in turn, could prove to increase the adenoma detection rate. The EndoRings is designed to fit specific endoscopes (as designated on the packaging), supplied sterile and is single use only. This device could prove to be an improvement of the current design.

Methods:

Colonoscopies will be performed by Dr. Douglas Rex and a number of sub-investigators. Data that will be assessed from each colonoscopy include the following:

1. APC (Adenoma per Colonoscopy)
2. Total adenomas detected
3. Total polyps detected
4. Polyp detection rate (PDR)
5. PPC (Polyp per Colonoscopy)
6. Effect on re-scope intervals
7. Cecal intubation rate
8. Comparison of the time required to reach the cecum
9. Comparison of the withdrawal and total procedure time
10. Effect of endoscopist experience on potential gain from using EndoRings
11. Patient comfort score
12. Problems encountered with equipment

- Slippage of Endorings™
- Difficulty intubating with Endorings™

Objectives:

The primary endpoint of the study will be the adenoma detection rate of the EndoRings Colonoscopy (EC) compared to that of the Standard Colonoscopy (SC). Complications will be recorded, but the study will not be powered for complications.

The study will help to establish a device that will result in improved adenoma detection rates when compared to a standard colonoscope.

Criteria:

Inclusion Criteria:

- Age ≥ 18
- Screening or Surveillance Colonoscopy
- Able to provide written informed consent

Exclusion Criteria:

- Prior history of surgical resection of the large intestine
- Known narrow colon or colon stenosis
- Personal history of Colorectal cancer
- History of Inflammatory bowel disease
- Familial adenomatous polyposis syndrome (FAP)
- Hyperplastic polyposis syndrome
- Referral for incomplete colonoscopy or polyp clearance

Randomization:

Once a patient has been screened to ensure inclusion and exclusion criteria have been met and has provided consent for participation in the study, the subject will be randomized in a 1:1 ratio. Randomization outcomes include the Standard Colonoscopy or the EndoRings Colonoscopy.

Statistical Analysis & Sample Size:

The primary analysis compares the adenoma detection rate between the EC group and the SC group. It is assumed that the proportion of patients with at least one adenoma would be 25% with SC and 35% with EC colonoscopy.

A two group Chi-Square test with a 0.05 one-sided significance level will have 80% power to detect a difference of 10% ADR between the two groups (odds ratio of 1.615) when the sample size in each group is 259, a total sample size of 518 subjects.

The final sample size will be 569 after adding the 10% expected drop-out rate.

Interim analysis will be performed after the 200th patient is enrolled to assess device performance and protocol amendment.

Data Integrity and Safety

All paper charts pertaining to the patient will be kept under lock and key in coordinators office away from the endoscopy area. The data entry will be performed into an excel file which will be stored on an internal network drive with encryption and password security. Only approved personnel by the IRB will have access to the file storage. This file will also not have any identifiable patient information. A study log with the identifiable information will be kept in a separate folder to enable the investigators to assist in any research audit. No procedural data except the date of examination will be entered into this log.

Any subject who wishes to withdraw from this investigation on his/her own accord and for whatever reason is entitled to do so without obligation and prejudice to further treatment. In addition, the Investigator may decide for reasons of medical prudence, to withdraw a subject. In either event, the Investigator will clearly document the date and reason(s) for the subject's withdrawal from this investigation in the CRF and should indicate whether or not he considers it was related to the study interventions.