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ClinicalTrials.gov ID: [Not yet assigned]

Study Identification

Unique Protocol ID:	17.135
Brief Title:	Optivista : I-SCAN OE for Optical Diagnosis of Small Colon Polyps
Official Title:	Optivista : I-SCAN OE for Optical Diagnosis of Small Colon Polyps
Secondary IDs:	

Study Status

Record Verification:	March 2018
Overall Status:	Recruiting
Study Start:	March 9, 2018 [Actual]
Primary Completion:	March 31, 2019 [Anticipated]
Study Completion:	March 31, 2019 [Anticipated]

Sponsor/Collaborators

Sponsor:	Centre hospitalier de l'Université de Montréal (CHUM)
Responsible Party:	Principal Investigator Investigator: Daniel Von Renteln [drenteln] Official Title: MD, Gastroenterologist Affiliation: Centre hospitalier de l'Université de Montréal (CHUM)
Collaborators:	Pentax Medical

Oversight

U.S. FDA-regulated Drug:	No
U.S. FDA-regulated Device:	No
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Approved Approval Number: 17.135 Board Name: Comité d'éthique de la Recherche du CHUM Board Affiliation: CHUM Phone: 514-890-8000 Email: Address: 900, St-Denis Street, R05-406 Montreal, Quebec

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Data Monitoring: No

FDA Regulated Intervention: No

Study Description

Brief Summary: The benefit of colonoscopy screening is based on the detection and removal of polyps neoplastic. However, the vast majority of found polyps do not harbor any risk of non-cancer neoplastic. The resection evaluation and histopathology of these polyps are associated with costs while the contribution to cancer prevention is limited. A new technique (Pentax Optivista) based on visual diagnosis of polyps has been introduced to reduce the costs associated with over-screening, and seems to be more efficient than the Pentax iScan technique.

Our research project aims to evaluate the new Optivista system compared to the iScan for his optical biopsy performance and interval agreement monitoring with pathology.

This is a prospective clinical trial for which participants are recruited directly from the colonoscopy clinic. The Participants will be randomized to be diagnosed by either Optivista or Pentax iScan. Endoscope withdrawal will be done in iScan 1 mode for patients randomized to iSan and in Optivista OE2 mode for patients randomized to Optivista.

For all polyps detected during the procedure, their size, location and morphology will be recorded according to the Paris classification after which all polyps will be resected per standard practices and sent for histopathologic evaluation.

Polyps that are between 1-10mm in size (diminutive and small polyps), there will be further assessed according to WASP, NICE, SANO and SIMPLE classifications using white light imaging and using an image-enhancing endoscopy technology that enhances visualisation of the polyp surface and vascular patterns.

Concordance between optical diagnosis and pathology monitoring according to recommendations will be presented as proportions with a 95% CI. We will present the features optical polyp diagnostic test for overall diminutive (1-5mm) polyps and by location in the colon (proximal, distal, colon and rectosigmoid segments). For outcome measures secondary factors, including factors that may influence the optical diagnosis, we will present proportional estimates with a 95% confidence interval (CI). Concordance between strategies is examined using a marginal homogeneity test (Stuart-Maxwell test). For the comparison of proportions, we will use a chi square test or a Fisher's exact two-sided test, as appropriate.

Detailed Description: NOTE : Detailed Description has not been entered.

Conditions

Conditions: Colo-rectal Cancer
Polyps of Colon

Keywords: Cancer prevention
Endoscopy
Gastroenterology

Study Design

Study Type:	Observational
Observational Study Model:	Cohort
Time Perspective:	Prospective
Biospecimen Retention:	None Retained
Biospecimen Description:	Biopsy of colorectal polyps detected during the observed colonoscopy.
Enrollment:	411 [Anticipated]
Number of Groups/Cohorts:	2

Groups and Interventions

Groups/Cohorts	Interventions
Optical diagnosis with Optivista Participants for which the optical diagnosis of detected colorectal polyps will be done with the new technique Pentax Optivista.	Diagnostic Test: Screening colonoscopy according to resect-and-discard strategy This strategy uses image enhancing techniques and optical diagnosis instead of histopathology assessment with 2 Pentax optical imaging systems (either Optivista or iScan).
Optical diagnosis with iScan Participants for which the optical diagnosis of detected colorectal polyps will be done with the oldest technique Pentax iScan.	Diagnostic Test: Screening colonoscopy according to resect-and-discard strategy This strategy uses image enhancing techniques and optical diagnosis instead of histopathology assessment with 2 Pentax optical imaging systems (either Optivista or iScan).

NOTE : Intervention Name should have no more than 60 characters.

NOTE : Intervention 'Screening colonoscopy according to resect-and-discard strategy' has not been included in any Arm/ Group Descriptions.

Outcome Measures

Primary Outcome Measure:

1. Concordance of Optical diagnosis with the pathology based reference standard
   The Optical diagnosis of polyps using Optivista or iScan will be compared with the pathology based reference standard.

   [Time Frame: 12 months]
2. Comparison of both of the technologies (Optivista and iScan) for Optical diagnosis
   [Time Frame: 12 months]

Secondary Outcome Measure:

3. Negative predictive value of rectosigmoid neoplastic polyps.
   Secondary outcomes and data collection include test characteristics, particularly the negative predictive value of rectosigmoid neoplastic polyps.

   [Time Frame: 12 months]

4. Concordance of biopsies and classifications
   Evaluation of outcomes for optical biopsies and the different classifications (Sano, NICE, SIMPLE and WASP) for polyps up to 10mm in size in conjunction with iScan and Optivista, and assessing possible variations across participating endoscopists.

   [Time Frame: 12 months]

5. Surveillance recommendation following the colonoscopy
   The proportion of patients for whom an immediate surveillance recommendation following the colonoscopy can be directly provided for each approach and how often histopathology polyp examination would have been avoided when using each strategy will be examined.

   [Time Frame: 12 months]

NOTE : Outcome Measure Description has not been entered.
NOTE : Normally only one Primary Outcome Measure is specified.

Eligibility

Study Population:	Participants will be recruited at the endoscopy unit at the CHUM, before undergoing an elective colonoscopy.
Sampling Method:	Probability Sample
Minimum Age:	45 Years
Maximum Age:	80 Years
Sex:	All
Gender Based:	No
Accepts Healthy Volunteers:	No
Criteria:	Inclusion Criteria:

- Signed informed consent
- Aged 45 to 80 years
- Indication for full colonoscopy

Exclusion Criteria:

- Known inflammatory bowel disease
- Active colitis
- Coagulopathy
- Familial polyposis syndrome
- Poor general health defined as an ASA class > 3
- Emergency colonoscopies

Contacts/Locations

Central Contact Person:	Catherine Péthel Telephone: 514-890-8000 Ext. 30917 Email: Catherine.Pethel.chum@ssss.gouv.qc.ca
Central Contact Backup:	
Study Officials:	Daniel von Renteln, MD, PhD Study Principal Investigator Centre Hospitalier Universitaire de Montréal, Research Center (CRCHUM)
Locations:	Canada, Québec Centre Hospitalier Universitaire de Montréal (CHUM) [Recruiting]

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Sub-Investigator: Benoit Panzini, MD

IPDSharing

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References

Citations:

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Available IPD/Information: