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Acetic-acid enhanced colonoscopy for the increase of polyp detection

Submission date	Recruitment status	[ ] Prospectively registered
06/07/2019	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/09/2019	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
21/08/2019	Digestive System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Detection and removal of polyps during colonoscopy is crucial for the prevention of colorectal cancer. Acetic-acid spaying up to the colonic mucosa could probably increase the adenoma detection rate.

Who can participate?
All patients who are undergoing colonoscopy for screening, for surveillance in follow-up of previous polypectomy or for diagnostic workup.

What does the study involve?
Spraying acetic-acid during colonoscopy up to mucosa of the colon to increase polyp detection.

What are the possible benefits and risks of participating?
Increase polyp detection without any possible adverse events to have been reported from acetic-acid usage in the colon.

Where is the study run from?
From 2 general hospitals in Greece - Gastroenterology departments.

When is the study starting and how long is it expected to run for?
The study starts in July 2019 and lasts up to October 2019.

Who is funding the study?
General Hospital of Nikaia-Piraeus "Agios Panteleimon".

Who is the main contact?
Georgios Trimponias MD (diek@nikaia-hosp.gr)

Contact information

Type(s)
Scientific

Contact name
Dr George Tribonias

Contact details
D. Mantouvalou 3
Nikaia,
Piraeus
Athens
Athens
Greece
18454
+302132077420
diek@nikaia-hosp.gr

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
AA1

Study information

Scientific Title
Prospective randomized comparison of acetic-acid assisted colonoscopy versus standard wight-light colonoscopy in the detection of sessile serrated adenomatous (SSA) lesions in the right colon

Acronym
AA1

Study objectives
The purpose of this study is to compare the additional diagnostic yield obtained by using acetic acid as a vital substance to improve the detection of sessile serrated adenomatous (SSA) polyps in the right colon during a colonoscopy. lesions at colonoscopy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/11/2018, the scientific-ethics board of the General Hospital of Nikaia-Piraeus "Agios Panteleimon" (D.Mantouvalou 3, Nikaia-Piraeus, Athens, 18454; epsymb@nikaia-hosp.gr; 00302132076235; 00302132077444), ref: 28/28-11-2018.

Study design

Multicentre interventional Prospective Randomized Trial

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Colorectal polyps detected by colonoscopy

Interventions
Patients who are scheduled for screening, surveillance or diagnostic colonoscopy will be recruited to the study and randomised to one of two groups. Each enrolled subject will undergo two "back-to-back" procedures limited to the examination of the right colon. Subjects in Group A (study group) will undergo a standard colonoscopy with high definition endoscope under white light. Once the right colon has been fully examined and all the detected polyps have been removed, the endoscopist will reach the cecum again and the patient will set in right lateral position . A solution with 250 cc normal saline and 25 cc acetic acid 2% will be used to fill in the right colon from the cecum to the hepatic flexure. The whole quantity of the solution will be inserted with the use of a water pump irrigator and all the air above the solution will be carefully suctioned in order for the largest surface of the mucosa to get in contact with the acetic acid solution. Afterwards, the patient will be positioned in the supine position for at least 30 seconds and then repositioned into the left lateral position. The endoscopist will suction as much as possible from the solution and then the second examination of the mucosa will start. Randomisation was done with SPSS program. There was not any treatment given to the patients. This study include only acetic acid spaying up to the colon mucosa for the detection of additional polyps.

Intervention Type
Supplement

Primary outcome(s)
The additional number of sessile serrated adenomatous (SSA) lesions detected at the level of the right colon after spraying of acetic acid and compared with the number of the same lesions detected after a second examination of the right colon using standard white-light high definition scopes and solution without acetic acid.

Key secondary outcome(s))
Measured as numbers of the events and the polyps detected through the examinations:
1. Number of new serrated lesions detected at second right colon examination in both studies group.
2. Number of overall serrated and/or adenomatous lesions in the whole colon.
3. Characteristic of lesions detected (size, morphology).
4. Complication rate.

Completion date
01/10/2029

Eligibility

Key inclusion criteria
1. The patient is undergoing colonoscopy for screening, for surveillance in the follow-up of the previous polypectomy or for diagnostic workup.
2. The patient must understand and provide written consent for the procedure.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. History of colonic resection.
2. Inflammatory bowel disease.
3. Personal history of a polyposis syndrome.
4. Suspected chronic stricture potentially precluding complete colonoscopy.
5. Diverticulitis or toxic megacolon.
6. History of radiation therapy to abdomen or pelvis.
7. Ulcer of the rectum.
8. Ischemic colitis or intestinal ischemia.
9. Inadequate bowel preparation (BBPS 3-6).

Date of first enrolment
01/07/2019

Date of final enrolment
01/10/2019

Locations

Countries of recruitment
Greece

Study participating centre
General Hospital of Nikaia-Piraeus "Agios Panteleimon"
D. Mantouvalou, Nikaia, Piraeus, Athens, 18454
Athens
Greece
18454

Study participating centre

Benizelion General hospital
Leoforos Knossou, Heraklion, Crete, Greece
Heraklion
Greece
71409

Sponsor information

Organisation
General Hospital of Nikaia-Piraeus "Agios Panteleimon"

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
General Hospital of Nikaia-Piraeus

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other