Evaluation of the Effectiveness of changing patient's position during the Withdrawal phase of Colonoscopy from left lateral Decubitus to Supine on increasing Adenoma Detection Rate (ADR)
Scientific title
Evaluation of the Effectiveness of changing patient's position during the Withdrawal phase of Colonoscopy from left lateral Decubitus to Supine on increasing Adenoma Detection Rate (ADR)

Public title
Evaluation of the effect of patient position change on the quality of colonoscopy

Purpose
Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 40 and 85 years Recommended to do screening colonoscopy

Exclusion criteria:
History of Colitis History of Colonic Polyposis Syndrome Familial history of Colorectal Cancer History of Colectomy History of Cholecystectomy History of Endoscopic Retrograde Cholangiopancreatography (ERCP) History of Bowel Disease History of Opium use Lack of Anesthesia for Colonoscopy Difference in received Anesthesia Drug Lack of Antispasmodic Medication for Colonoscopy Differences in received Antispasmodic Drug Difference in dose of received Antispasmodic Drug Absence of a Nurse during Colonoscopy Presence of a second physician during Colonoscopy Musculoskeletal problems in Patient Patient Dissatisfaction to Participate in the Study Disapproval of reaching to Cecum by physician or requiring more than 20 minutes to reach the Cecum Inadequate Bowel Preparation (The Boston Bowel Preparation Scale less than 5) Occurrence of any Side Effects During the Colonoscopy procedure

Age
From 40 years old to 85 years old

Gender
Both

Phase
N/A

Groups that have been masked
- Participant

Sample size
Target sample size: 624

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will assign to study groups due to the random blocks method. By using a website(www.randomization.com) and considering one block and total sample size 624, all patients with a 1 to 1 ratio, randomly assigned to one of the study groups according to the patient's number. During the colonoscopy, at the beginning of the withdrawal phase, the physician will use the patient's list and put a patient in a considered group according to patient's number and continue the procedure.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study is a single-blind study. Due to anesthesia, the patients are blind to the group they are in. The physician performing the colonoscopy is blind to the patient group up to the beginning of the withdrawal phase of colonoscopy, but because of the nature of the colonoscopy process and the physician's direct view of how the patient is positioned, it is not possible to blind the physician during the withdrawal phase of colonoscopy.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Health Research Institute - Babol University of Medical Sciences

Street address
Ganj Afroz St, Babol University of Medical Sciences, Health Research Institute

City
Babol

Province
Mazandaran

Postal code
4717641367

Approval date
2020-03-14, 1398/12/24

Ethics committee reference number
IR.MUBABOL.HRI.REC.1398.370

Health conditions studied

1

Description of health condition studied
Adenoma Detection Rate (ADR)

ICD-10 code
K63.5

ICD-10 code description
Polyp of colon

Primary outcomes
Description
Adenoma Detection Rate

Timepoint
The outcome variable will be calculated after doing colonoscopy for all specimens for both study groups.

Method of measurement
The number of adenomas observed in the withdrawal phase for each patient will be recorded in the patient’s pre-prepared form. After doing colonoscopy of all specimens, we calculate the adenoma detection rate for each group. It is the proportion of patients in whom more than one adenoma has been observed to all patients undergoing colonoscopy and will be calculated separately for each group.

Secondary outcomes

1
Description
The Size of a Detected lesion

Timepoint
During Colonoscopy Procedure

Method of measurement
during the colonoscopy procedure, the diameter of the detected lesion will be measured in comparison to the biopsy forceps and will be recorded in the patient-specific form.

2
Description
Patient's feeling about Abdominal Fullness after Colonoscopy

Timepoint
10 minutes after the patient recovered.

Method of measurement
10 minutes after the patient recovered, we will ask him or her about abdominal fullness by using a prepared question which has 5 option from no abdominal fullness to painful fullness.

Intervention groups

1
Description
Intervention group: positioning the patient in supine position in the withdrawal phase of colonoscopy. At the beginning of the withdrawal phase of colonoscopy, patients will be switched from the left lateral position to the supine position by helping from the nurse, and the physician initiates the withdrawal phase of colonoscopy.

Category
Diagnosis

2
Description
Control group: positioning the patient in the left lateral decubitus position in the withdrawal phase of colonoscopy. Patients will remain in the same position lying on their left side and the doctor will initiate the withdrawal phase of colonoscopy.

Category
Diagnosis

Recruitment centers

1
Recruitment center
Name of recruitment center
Ayatollah Rohani Hospital
Full name of responsible person
Javad Shokri Shirvani
Street address
Ayatollah Rohani Hospital, University Sq, Ganjafroz Street
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2
Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
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Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Reza Ghadimi
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vice-chancellor for research & technology, Ganjafroz Avenue, Daneshgah Square, Babol
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Phone
+98 11 3219 7667
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rezaghanimi@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic
Person responsible for general inquiries
Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Javad Shokri Shirvani
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
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+98 11 1223 8284
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drshokrij@mubabol.ac.ir
Sharing plan
Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
Epidemiological findings and gathered data from colonoscopy and pathology results after making participants anonymous are sharable.

When the data will become available and for how long
The start of access is 6 months after the publication of results.

To whom data/document is available
The data are accessible to other scientists.

Under which criteria data/document could be used
The researcher must say the data are used in which research and specify the goal of the research.

From where data/document is obtainable
For data access refer to the corresponding author.

What processes are involved for a request to access data/document
Request for data access is sent to the corresponding author and after investigation, if seeming fit, the data will be shared

Comments