

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

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)

Protocol summary

Study aim

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

Design

Clinical trial with intervention and control groups, single blinded, randomized by random blocks method, sample size 624 with a 1:1 ratio between groups.

Settings and conduct

study will be executed in two hospitals affiliated to Babol University. Eligible patients, after physician confirms reaching the cecum, will be placed into one of the study groups according to a pre-prepared list and the withdrawal phase of colonoscopy will be done and all of the findings during the colonoscopy will be registered in a pre-prepared form.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 40-85 years old that are advised to do a screening colonoscopy Exclusion criteria: a history of digestive disorders, history of intervention on the digestive system, musculoskeletal disorders that ban position change, Dissatisfaction of the patient to participate, lack of confirmation of reaching the cecum or duration of reaching the cecum more than 20 minutes, insufficient bowel preparation quality (BBPS<5) and the occurrence of any side effects during colonoscopy

Intervention groups

Intervention group: Positioning the patient in a supine position. After confirming reaching the cecum, those who are in this group according to the pre-prepared list will be switched from a lateral decubitus position to supine By the nurse and the physician performs the withdrawal phase. Control group: positioning the patient in left lateral decubitus position. After confirming reaching the cecum, those who are in this group according to the pre-prepared list will be in left lateral decubitus position

without any change and the physician performs the withdrawal phase.

Main outcome variables

Adenoma Detection Rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110721007080N5**

Registration date: **2020-05-04, 1399/02/15**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-04, 1399/02/15**

Update count: **0**

Registration date

2020-05-04, 1399/02/15

Registrant information

Name

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Name of organization / entity

Babol University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2021-06-22, 1400/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

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 Colonoscopy in the past year History of Inflammatory 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

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

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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

1

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

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Sponsors / Funding sources

1

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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

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Person responsible for updating data

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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