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
Javad Shokri Shirvani
Name of organization / entity
Babol University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 11 1223 8284
Email address
drshokrij@mubabol.ac.ir

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
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

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
Javad Shokri Shirvani
Street address
Ayatollah Rohani Hospital, University Sq, Ganjafroz Street
City
Babol
Province
Mazandaran
Postal code
47176-47745
Phone
+98 11 3223 8301
Email
info@mubabol.ac.ir

2

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Javad Shokri Shirvani
Street address
shahid Beheshti Hospital, Ganjafroz Street
City
Babol
Province
Mazandaran
Postal code
4716681451
Phone
+98 11 3225 2071
Email
beheshti@mubabol.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Reza Ghadimi
Street address
vice-chancellor for research & technology, Ganjafrooz Avenue, Daneshgah Square, Babol
City

Babol
Province
Mazandaran
Postal code
۴۷۱۷۶-۴۷۷۵۴
Phone
+98 11 3219 7667
Email
rezaghadimi@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
Internal Medicine
Street address
Rouhani haspital, Danesgah Square, Ganjafrooz Avenue, Babol
City
Babol
Province
Mazandaran
Postal code
۴۷۱۷۶-۴۷۷۴۵
Phone
+98 11 1223 8284
Fax
+98 11 1223 8284
Email
drshokrij@mubabol.ac.ir

Person responsible for scientific 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
Internal Medicine
Street address
Rouhani haspital, Danesgah Square, Ganjafrooz Avenue, Babol
City
Babol
Province
Mazandaran
Postal code
۴۷۱۷۶-۴۷۷۴۵
Phone
+98 11 1223 8284
Fax
+98 11 1223 8284
Email
drshokrij@mubabol.ac.ir

Person responsible for updating data

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
Internal Medicine
Street address
Rouhani haspital, Danesgah Square, Ganjafrooz Avenue, Babol
City
Babol
Province
Mazandaran
Postal code
۴۷۱۷۶-۴۷۷۴۵
Phone
+98 11 1223 8284
Fax
+98 11 1223 8284
Email
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