

The role of walking in colonoscopy preparation

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Registration date 22/08/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/10/2023	Condition category Surgery	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

background and study aims

A colonoscopy is where the bowel is examined using a camera. One of the most difficult aspects of colonoscopies is adequate bowel preparation, which involves cleansing of the colon. If the preparation is inadequate, the procedure may have to be repeated, which leads to increased colonoscopy costs, increased risk of complications and disagreement from patients. Therefore, there is the need to develop new methods for cleansing the intestine and bowel region. It appears that performing slow-paced exercise can improve the quality of bowel preparation for colonoscopy.

This study aims to look at the effect of walking as part of colonoscopy preparation.

Who can participate?

Patients aged 18-70 who have been referred to the Razi Hospital in Rasht, Iran for a colonoscopy for any reason

What does the study involve?

Participants will be randomised into the walking and non-walking groups. Participants in both groups will be asked to prepare for their colonoscopy as usual using guidelines based around eating and drinking. The non-walking group will be asked to only do this, whereas the walking group will be provided with instructions to walk at different periods of the day. Both groups will have their steps monitored for 24 hours before the colonoscopy using a smart wristband.

What are the possible benefits and risks of participating?

The possible benefit of participating is that for those in the walking group, the addition of walking to colonoscopy preparation may help with an exact diagnosis with no need to repeat the procedure. There are no known risks to participants taking part in this study.

Where is the study run from?

Razi Hospital, Rasht, Iran

When is the study starting and how long is it expected to run for?

June 2018 to October 2018

Who is funding the study?

Guilan University of Medical Sciences (Iran)

Who is the main contact?
Professor Fariborz Mansour-Ghanaei
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
P-3-1321247

Study information

Scientific Title
A single-blinded clinical trial of the role of walking in the level of colonoscopy preparation in patients referring to the Razi Hospital Endoscopy Ward

Study objectives
Null hypotheses:
1. The average steps and Boston score in terms of socio-demographic characteristics among the two groups (walking and non-walking) has no difference
2. The average steps and Boston score in terms of (main complaint, bowel frequency status, surgery history, chronic diseases) among the two groups (walking and non-walking) has no difference
3. The average steps and Boston score in terms of time of colonoscopy, unsuccessful colonoscopy among the two groups (walking and non-walking) has no difference

Ethics approval required
Old ethics approval format

Ethics approval(s)

This study is approved by the ethics committee of Guilan University of Medical Sciences, Rasht, Iran, 11/06/2018, IR.GUMS.REC.1397.113

Study design

Interventional single-blind randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Home

Study type(s)

Screening

Participant information sheet

Not available in web format, please use the following contact details to request a participant information sheet: fmansourghanaei@gmail.com

Health condition(s) or problem(s) studied

Colonoscopy

Interventions

Participants will be randomised using free online software into two groups - the walking and non-walking (control) group.

The walking group will be asked to prepare for their colonoscopy using the following method:

1. Eat breakfast at 8 am in the morning, without milk and dairy.
2. From 8 am to 12 pm, only drink clear and smooth fluids of 8 to 10 glasses (such as water, tea, soup and lemon juice). Following this, walk for 5 minutes.
3. Between 12 to 1 pm, eat a light lunch including a cooked chicken breast and a Toast slice with 2 bisaccholate pills. Following this, walk for 5 minutes.
4. After this, do not eat any solid foods until the colonoscopy (including watermelon, melon, fruit, ash and soup).
5. Dissolve 3 of Polyethylene glycol powder (COLOTRANS-E, distributor DARYAN TEJARAT) into 3 liters of water (approximately 12 to 13 glasses full) and after about 15 minutes to 20 minutes, take 1 glass of this solution. Following this, walk for 5 minutes.
6. At 6 pm, take 2 bisacodyl tablets. Following this, walk for 5 minutes.
7. After completing the COLOTRANS-E solution, drink whatever you wish clear liquids such as water, sugar juice, sweet tea, honey tea, perfectly flattened juice, ice water or soup. Following this, walk for 5 minutes.
8. Around 2 hours after having the 3 packs of powder for about 2 hours, dissolve another 2 packs of powder in two liters of water (about 8 glasses) and drink from 9 pm every 15 to 20 minutes. Following this, walk for 5 minutes.
9. When the solution has been drank, do not eat anything and fast until colonoscopy is completed.

The non-walking group will be asked to prepare for their colonoscopy using the following method:

1. Eat breakfast at 8 am in the morning, without milk and dairy.
2. From 8 am to 12 pm, only drink clear and smooth fluids of 8 to 10 glasses (such as water, tea, soup and lemon juice).
3. Between 12 to 1 pm, eat a light lunch including a cooked chicken breast and a Toast slice with 2 bisaccholate pills.
4. After this, do not eat any solid foods until the colonoscopy (including watermelon, melon, fruit, ash and soup).
5. Dissolve 3 of Polyethylene glycol powder (COLOTRANS-E, distributor DARYAN TEJARAT) into 3 liters of water (approximately 12 to 13 glasses full) and after about 15 minutes to 20 minutes, take 1 glass of this solution.
6. At 6 pm, take 2 bisacodyl tablets.
7. After completing the COLOTRANS-E solution, drink whatever you wish clear liquids such as water, sugar juice, sweet tea, honey tea, perfectly flattened juice, ice water or soup.
8. Around 2 hours after having the 3 packs of powder for about 2 hours, dissolve another 2 packs of powder in two liters of water (about 8 glasses) and drink from 9 pm every 15 to 20 minutes.
9. When the solution has been drank, do not eat anything and fast until colonoscopy is completed.

Both groups will be provided with a smartband wristband (Xiaomi Mi Band 2), which will show the number of steps taken. Participants will be asked to consent to the trained questioner downloading the Mi Fit application onto their phones for the transfer of information from the wristband to their phone.

Intervention Type

Behavioural

Primary outcome measure

Boston score as a measure of bowel preparation for the colonoscopy, assessed using the Boston criteria (Boston Bowel Preparation Scale) following the colonoscopy.

Secondary outcome measures

Time taken to perform the colonoscopy, measured using a digital washing during the colonoscopy.

Overall study start date

05/06/2018

Completion date

21/10/2018

Eligibility

Key inclusion criteria

1. Alert (elderly individuals should have an alert attendant at home)
2. Aged 18-70 years old
3. Requiring colonoscopy for any reason at Razi Hospital (Rasht, Iran)

Participant type(s)

Other

Age group

Mixed

Lower age limit

18 Years

Upper age limit

70 Years

Sex

Both

Target number of participants

131

Key exclusion criteria

1. Hospitalised
2. Hip and knee replacement
3. Motor problems

Date of first enrolment

12/06/2018

Date of final enrolment

14/10/2018

Locations**Countries of recruitment**

Iran

Study participating centre**Razi Hospital Colonoscopy Ward**

Gastrointestinal and Liver Diseases Research Center, Guilan University of Medical Sciences, Razi Hospital, Sardar-Jangle Ave., Rasht, Iran

Rasht

Iran

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Sponsor information**Organisation**

Guilan University of Medical Sciences

Sponsor details

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Sponsor type

University/education

Website

<http://www.gums.ac.ir/default-52.aspx>

ROR

<https://ror.org/04ptbrd12>

Funder(s)

Funder type

Not defined

Funder Name

Not applicable

Results and Publications

Publication and dissemination plan

Planned publication a high-impact peer-reviewed journal

Intention to publish date

25/02/2019

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		09/10/2023	10/10/2023	Yes	No