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The role of walking in colonoscopy preparation

Submission date
17/07/2018

Recruitment status
No longer recruiting

Registration date
22/08/2018

Overall study status
Completed

Last Edited
10/10/2023

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

ackground 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

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Interventional single-blind randomised controlled trial

Study type(s)
Screening

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

Key secondary outcome(s)
Time taken to perform the colonoscopy, measured using a digital washing during the colonoscopy.

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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
70 Years

Sex
All

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
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41448-95655

Sponsor information

Organisation
Guilan Univercity of Medical Sciences

ROR
https://ror.org/04ptbrd12

Funder(s)

Funder type
Not defined

Funder Name
Not applicable

Results and Publications

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