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Study of the impact of one day versus three days of diet on bowel preparation quality before colonoscopy

Submission date
28/11/2021

Recruitment status
No longer recruiting

Registration date
08/12/2021

Overall study status
Completed

Last Edited
18/10/2022

Condition category
Digestive System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Colonoscopy represents the gold standard of screening programs for the early detection of lesions that could develop into cancerous or benign (non-cancerous) tumors. The quality of bowel preparation is reported to significantly affect two important performance measures for colonoscopy, the adenoma detection rate (a type of benign tumour that develops in glandular cells) and the cecal intubation rate (reaching the caecum, and so completing the examination of the entire colon). A one-day low residual (low-fibre) diet is recommended before colonoscopy. This study aims to compare the impact of following a low residual diet for 3 days versus 1 day on the quality of the bowel preparation and the satisfaction and adherence of outpatients undergoing colonoscopy.

Who can participate?
Patients aged 18 years and older who are scheduled to have a colonoscopy with bowel preparation.

What does the study involve?
Eligible patients will be allocated to one of two groups, with an equal chance of being in either group (like tossing a coin). Based on the group to which they were assigned, participants will be informed about the type of diet to follow. Participants in the first group will be asked to follow a 1-day structured low-residue diet (LRD) for 1 day prior to their colonoscopy and those in the other group will be asked to follow a structured LRD for 3 days prior to their colonoscopy. Allowed foods in the LRD will be pasta or rice (not whole), meat, fish, milk, eggs, cheese, ham, and cold cuts, bread (not brown or rye bread), and potatoes. Forbidden foods in the LRD will be vegetables, legumes, and fruits.

What are the possible benefits and risks of participating?
The benefit of this study is receiving an excellent bowel cleansing that is necessary to improve the adenoma detection rate and diagnosis. There are no risks for participants other than those related to colonoscopy.

Where is the study run from?
Società Italiana Endoscopia Digestiva (Italy)

When is the study starting and how long is it expected to run for?
November 2013 to March 2021

Who is funding the study?
Società Italiana Endoscopia Digestiva (Italy)

Who is the main contact?
Prof. Paola Iovino
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Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
One-day versus three-days low residue diet and bowel preparation quality before colonoscopy: a multicenter, randomized, controlled trial

Study objectives
To compare the impact of a 3-days versus 1-day low residual diet on the quality of the bowel preparation and the satisfaction and adherence of outpatients undergoing colonoscopy.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 03/02/2014, Ethics Committee of the G. Rummo Hospital of Benevento (Segreteria T.S. A., Via Marconi n. 66 – 80059 Torre del Greco, Italy; +39 (0)81/3174206; cometicocampaniasud@aslnapoli3sud.it), ref: n.135

Primary study design
Interventional

Study design
Multicenter parallel randomized controlled single-blinded trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Bowel preparation quality before colonoscopy

Interventions
The study informed consent was collected and demographics and medical history recorded on the data collection form. Eligible patients were randomized to one of the following two groups: 1-day structured low-residue diet (LRD) or 3-days structured LRD. Based on the group to which they were assigned, patients were informed both orally and by means of leaflets about the type of diet to be performed. Specifically, the differences between the two arms consisted of the duration of the LRD. Allowed foods were: pasta or rice (not whole), meat, fish, milk, eggs, cheese, ham and cold cuts, bread (not brown or rye bread), potatoes. Forbidden foods were: vegetables, legumes, fruits. All patients received the information sheet for participation in the study and the assessment of the standardized questionnaire of satisfaction for colonoscopy preparation. Demographic data, comorbidities, drug therapy, surgical history, number of evacuations per week, indications for colonoscopy, type of bowel preparation, mode of dose intake, amount of bowel preparation taken, time in hours between the end of preparation and start of colonoscopy, type of sedation, and endoscopic diagnosis were collected.

Intervention Type
Behavioural

Primary outcome(s)
The proportion of subjects with a satisfactory degree of bowel cleanliness with a Score 2 and 3 on the Boston scale in each segment on the day of colonoscopy

Key secondary outcome(s)
1. Patient satisfaction measured using a standardized questionnaire of satisfaction for colonoscopy preparation on the day of colonoscopy
2. Adherence to the prescribed diet. measured using patient interview on the day of colonoscopy

Completion date
01/03/2021

Eligibility

Key inclusion criteria

1. Aged ≥18 years
2. Scheduled to have a colonoscopy with bowel preparation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
289

Key exclusion criteria
1. Aged <18 years
2. Have undergone a previous proctocolectomy
3. Undergoing a colonoscopy without bowel preparation or in whom the preparation was contraindicated
4. Dietary regimen to be adopted before preparation was contraindicated
5. Refused to provide informed consent
6. Unable to understand the instructions and explanations relating to the purpose and design of the study

Date of first enrolment
01/09/2015

Date of final enrolment
30/03/2016

Locations

Countries of recruitment
Italy

Study participating centre
G. Rummo Hospital
Gastroenterology and Digestive Endoscopy Unit
Via Pacevecchia, 53
Benevento
Italy
82100

Study participating centre
AOU San Giovanni di DIo e Ruggi D'Aragona
Gastroenterology and Digestive Endoscopy Unit
Via San Leonardo, 1
Salerno
Italy
84131

Study participating centre
Maresca Hospital
Gastroenterology and Digestive Endoscopy Unit
Via Montedoro, 53
Torre del Greco
Italy
80059

Sponsor information

Organisation
Società Italiana Endoscopia Digestiva

Funder(s)

Funder type
Research organisation

Funder Name
Società Italiana Endoscopia Digestiva - Campania region

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Paola Iovino (piovino@unisa.it). The data will be available for about 1 year in the form of an SPSS database and will involve all the data collected during the study and the statistical analysis carried out.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			18/10/2022	No	No