**ClinicalTrials.gov PRS DRAFT Receipt (Working Version)**
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**ClinicalTrials.gov ID: NCT05397158**

## Study Identification

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|---|---|
| Unique Protocol ID: | YuHe |
| Brief Title: | Optimization of Intestinal Preparation in Older Patients |
| Official Title: | Study on Optimization of Intestinal Preparation Before Colonoscopy in Older Patients |
| Secondary IDs: | |

## Study Status

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|---|---|
| Record Verification: | July 2022 |
| Overall Status: | Completed |
| Study Start: | September 1, 2021 [Actual] |
| Primary Completion: | June 30, 2022 [Actual] |
| Study Completion: | July 31, 2022 [Actual] |

## Sponsor/Collaborators

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| Sponsor: | Beijing Tongren Hospital |
| Responsible Party: | Sponsor |
| Collaborators: | |

## Oversight

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|---|---|
| U.S. FDA-regulated Drug: | No |
| U.S. FDA-regulated Device: | No |
| U.S. FDA IND/IDE: | No |
| Human Subjects Review: | Board Status: Approved<br>Approval Number: TRECKY2021-227<br>Board Name: Ethics Committee of Beijing Tongren Hospital<br>Board Affiliation: Capital Medical University<br>Phone: +86-010-58268419<br>Email: qinmingzhao58@163.com<br>Address:<br><br>Beijing Tongren Hospital, Capital Medical University, 1 Dongjiaominxiang street, Dongcheng District, Beijing, People's Republic of China |
| Data Monitoring: | |

## Study Description

Brief Summary: Older adults are susceptible to intestinal tumors. Colonoscopy can screen colorectal cancer, adenoma and other diseases. There is a large demand for colonoscopy in the older adults, and the risk during peri-colonoscopy period is high. According to the common intestinal preparation methods and the characteristics of the older adults, the investigators propose a modified method, that is single administration of low dose polyethylene glycol (PEG). Specifically, take 30ml lactulose in the morning 1 day before the examination, and eat without residue in lunch and dinner, Take 2L PEG in the morning of the examination day and fast at breakfast and lunch of the day. Taking 4L PEG in 2 days as the control group. The fasting and diarrhea period is shorter in the modified group than that in the control group, and the dose of PEG is less. Lactulose, a laxative, is taken one day before the examination, and the intestinal preparation time is longer than that of single administration. The situation of comfort, sleep and fecal incontinence during the intestinal preparation of the two groups will be compared. The results of electrolyte, blood glucose and B-type brain natriuretic peptide between the two groups will be also compared. The effect of intestinal preparation will be evaluated by the standardization of Boston intestinal preparation scale, and endoscopist blind method will be used in colonoscopy.

Detailed Description: The participants in control group take 2L PEG the day before the examination, fast at dinner (participants without diabetes) and eat without residue (participants with diabetes). Participants take 2L PEG again in the morning of the examination day, and fasted at breakfast and lunch of the day.

## Conditions

Conditions: Colonoscopy
Older Adults

Keywords: colonoscopy
intestinal preparation
older adults

## Study Design

Study Type: Interventional

Primary Purpose: Diagnostic

Study Phase: N/A

Interventional Study Model: Parallel Assignment

Number of Arms: 2

Masking: Single (Outcomes Assessor)
Endoscopist blind method.

Allocation: Randomized

Enrollment: 312 [Actual]

## Arms and Interventions

| Arms | Assigned Interventions |
|---|---|
| Experimental: Single administration of low dose polyethylene glycol group | Procedure/Surgery: single administration of low dose polyethylene glycol |

| Arms | Assigned Interventions |
|---|---|
| The patients take 30ml lactulose in the morning 1 day before the examination, and eat without residue in lunch and dinner; Take 2L PEG in the morning of the examination day and fast at breakfast and lunch of the day. | Patients in single administration of low dose polyethylene glycol (PEG) group: Take 30ml lactulose and 2L PEG. Patients in control group: Take 4L PEG. |
| Active Comparator: control group<br>The patients in control group take 2L PEG the day before the examination, fast at dinner (patients without diabetes) and eat without residue (patients with diabetes). Patients take 2L PEG again in the morning of the examination day, and fasted at breakfast and lunch of the day. | Procedure/Surgery: single administration of low dose polyethylene glycol<br>Patients in single administration of low dose polyethylene glycol (PEG) group: Take 30ml lactulose and 2L PEG. Patients in control group: Take 4L PEG. |

## Outcome Measures

Primary Outcome Measure:

1. Intestinal preparation Cleanliness assessment
   The effect of intestinal preparation will be evaluated by Boston Intestinal Preparation Scale.The minimum score is 0#and the maximum score is 9. Higher scores mean a better outcome. Endoscopist blind method will be used.

   [Time Frame: Up to 1 hour]

Secondary Outcome Measure:

2. Blood potassium level before and after intestinal preparation
   Blood potassium in mmol/L.

   [Time Frame: Up to 1 week]
3. Blood sodium level before and after intestinal preparation
   Blood sodium in mmol/L.

   [Time Frame: Up to 1 week]
4. Blood glucose level before and after intestinal preparation
   Blood glucose in mmol/L.

   [Time Frame: Up to 1 week]
5. B-type brain natriuretic peptide (BNP) level before and after intestinal preparation
   BNP in pg/ml.

   [Time Frame: Up to 1 week]
6. The situation of comfort during the intestinal preparation
   Comfort situation questionnaire. The score of comfort questionnaire is 1 to 10, 1 represents extremely uncomfortable and 10 represents very comfortable.

   [Time Frame: Two days]
7. The situation of sleep during the intestinal preparation
   Sleep situation questionnaire. The length of sleep in hour, the number of awakening, the number of urination and defecation.

   [Time Frame: One day]
8. The situation of fecal incontinence during the intestinal preparation
   Fecal incontinence questionnaire. Does the patient have fecal incontinence and the number of fecal incontinence.

   [Time Frame: One day]

## Eligibility

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|---|---|
| Minimum Age: | 50 Years |
| Maximum Age: | |
| Sex: | All |
| Gender Based: | |
| Accepts Healthy Volunteers: | No |
| Criteria: | Inclusion Criteria:<br>• Age≥ 50y<br>• Colonoscopy is planned<br>• Willing to participate<br>Exclusion Criteria:<br>• Age#50y<br>• Unwilling to participate<br>• Missing data |

## Contacts/Locations

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| Central Contact Person: | Yu He, MD<br>Telephone: +86-010-58268320<br>Email: bluelight323@126.com |
| Central Contact Backup: | Qi Liu, MD<br>Telephone: +86-010-58268731<br>Email: liuqi6612@126.com |
| Study Officials: | NOTE : Study Official is required by the WHO and ICMJE. |
| Locations: | **China, Beijing**<br>Beijing Tongren Hospital<br>Beijing, Beijing, China<br>Contact: Yu He, MD +86-010-58268320 bluelight323@126.com |

## IPDSharing

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| Plan to Share IPD: | No |

## References

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| Citations: | |
| Links: | |
| Available IPD/Information: | |