IRB# **2000031169**
NCT05054036

Compound Authorization and Consent for Participating in a Research Study
Yale University School of Medicine-Yale New Haven Hospital

Study title: Efficacy, Safety and Tolerability of MoviPrep® versus GoLYTELY® bowel preparation in hospitalized patients undergoing colonoscopy: a randomized control trial

Principal Investigator: Darrick K. Li, MD, PhD

Phone Number: 203-285-4506

Funding Source: None

Research Study Summary:

- We are asking you to join a research study.
- The purpose of this research study is to determine if a low volume bowel preparation is similar in quality of bowel cleansing as traditional high volume bowel preparation in hospitalized patients who are being prepared for colonoscopy.
- Study procedures will include:
  - A questionnaire after completing your bowel preparation that assesses the tolerability of the bowel preparation
  - Your scheduled colonoscopy
- 4 visits with our team are required while you are hospitalized.
- The visits will take approximately 2 hours in total.
- This study involves only standard medical procedures, so the risks to you from being in the study are very low. There is a risk that one or the other bowel preparation might be less effective in clearing the bowel to make a complete diagnosis. Besides this, there are no risks incurred with the study that are beyond those associated with the clinically warranted procedure (bowel preparation and colonoscopy).
- The study may have no benefits to you. However, the information we gather may help other hospitalized patients undergoing colonoscopy in the future.
- There are other choices available to you outside of this research. You can proceed with getting a high volume bowel preparation for cleansing prior to colonoscopy without being in a study.
- Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You can also change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.
- If you are interested in learning more about this study, please continue reading, or have someone read to you, the rest of this document. Take as much time as you need before you make your decision. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will have to sign this form.

Why is this study being offered to me?

You are being asked to take part in a research study because you are having a colonoscopy procedure while you are being hospitalized. We are looking for 450 participants to be part of this research study at

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Yale-New Haven Hospital and Bridgeport Hospital. Your decision about being in this study will have no effect on the quality of your present or future health care. Please ask questions if there is any information about this study you do not understand. You may have a copy of this form to discuss with your doctors and family before deciding whether to be in the study. Your decision to join this study is voluntary.

A description of this study will be available on www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Who is paying for the study?

This research is not being funded by any external source.

What is the purpose of this study?

The purpose of the study is to determine if the use a low volume bowel preparation (2 liters) called MoviPrep® results in similar quality of bowel preparation compared to standard high volume bowel preparation (4 liters) called GoLYTELY® among hospitalized patients undergoing colonoscopy. The quality of bowel preparation is important and poor bowel preparation can lead to increased rates of complications, missed diagnoses, and longer hospital stays. However, hospitalized patients are at risk of poor bowel preparation because they are often unable to tolerate the large volume required by standard bowel preparation. GoLYTELY® is currently the most common bowel preparation used prior to colonoscopy in hospitalized patients.

In this study, we want to learn if a low volume bowel preparation can lead to similar quality of bowel preparation compared to standard high volume bowel preparation but with increased tolerability, i.e. less symptoms of nausea, vomiting, abdominal bloating and pain while taking the preparation. Both bowel preparations are approved by the Federal Drug Administration (FDA) for use for bowel cleansing prior to colonoscopy.

What does this study involve?

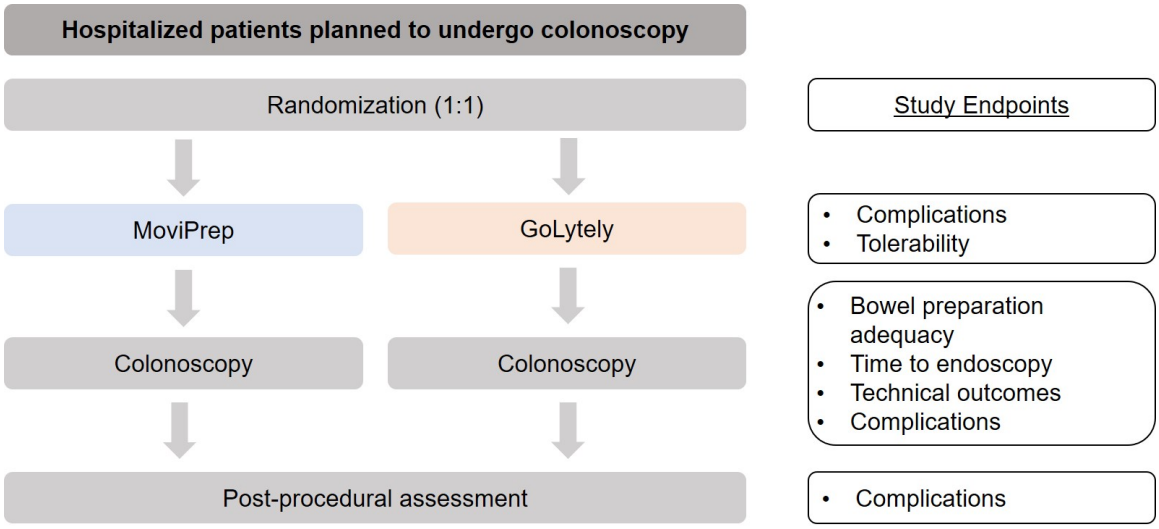
When your hospital team decides that you will need to undergo a colonoscopy during your hospitalization, a gastroenterologist or research coordinator will talk to you about the procedure and about the study. You will have the opportunity to ask any questions. If you decide to join the study, you will be asked to sign this consent form. In this study, we want to learn if the use of the low volume bowel preparation, MoviPrep® is associated with similar quality of bowel cleansing but with improved tolerability compared to the standard high volume bowel preparation, GoLYTELY®. You will have a 50% chance to be assigned to either receiving the low volume bowel preparation, MoviPrep® or the standard high volume bowel preparation, GoLYTELY®. This assignment is random, which means by chance, like tossing a coin. The endoscopist will not be blinded to which bowel preparation you receive.

After you complete the bowel preparation but before the colonoscopy, a gastroenterologist or research coordinator will talk to you to assess your experience of the bowel preparation and also ask you to fill out a brief nine question questionnaire about the bowel preparation. In addition, you will also receive standard of care which includes blood tests drawn to check your electrolytes and kidney function and a possible electrocardiogram.

During the colonoscopy, we will record images from the colonoscopy but without information that could identify you. For the study, we collect certain information on your colonoscopy, such as the quality of the bowel preparation, how long it took, and how easy it was to perform.

After your procedure, you will receive standard medical care, which includes a post-procedure visit in your hospital room within 1-3 days from a gastroenterologist to check on your recovery. At this point, your part in the study will end. Follow-up data, including results of the procedure and the length of your hospitalization, and delayed complications will also be collected through review of medical records.

Trial Design



What are the risks involved with being enrolled in this study?

This study involves only standard medical procedures, so the risks to you from being in the study are very low. There is a risk that one or the other bowel preparation might be less effective in clearing the bowel to make a complete diagnosis. Aside from this, there are no risks incurred with the study that are beyond those associated with the clinically warranted procedure (bowel preparation and colonoscopy). The bowel preparations involved in this study are both FDA-approved bowel cleansing medications that are used widely in clinical practice and as such there are no risks incurred in this study with regards to bowel preparation beyond what is standard of care. In theory, there is a minimal risk associated with electrolyte abnormalities associated with a low volume bowel preparation. However, there has been no study to show that there is an increased risk of this with MoviPrep® over standard GoLYTELY®. Furthermore, for a benefit of possibly increased tolerability, this minimal risk seems justifiable.

Risks and discomforts involved with this study include the following:

- Nausea, vomiting, abdominal bloating associated with the bowel preparation.
- Electrolyte disturbances and dehydration associated with the bowel preparation.
- Abdominal pain and cramping, bleeding, infection, and rare risks of perforation requiring surgical repair associated with the colonoscopy.
- There is a small risk that your health information could be disclosed outside of the study team.
- A study risk could be anxiety about being a study participant.

You should report any problems you may have to the study team.

Pregnancy:

Pregnant women may not take part in this research study. If you think you may be pregnant, please tell your endoscopy doctor. Pregnancy testing will be done prior to procedure by standard of care in all women who are of child bearing age.

How will I know about new risks or important information about the study?

We will tell you about new scientific findings related to this research as they become known. You can then decide again if you want to continue being in this study.

Are there any benefits from participating in this study?
You might not benefit from being in this research study. We hope to gather information that may help other hospitalized patients undergoing colonoscopy in the future.

Are there any costs to participation?
There are no costs to your participation in this study. The medical care that you will receive in this study is considered standard of care for your situation and thus would be recommended regardless of your decision to participate in this study. These costs will be billed to you or your insurance.

Will I be paid for participation?
You will not be paid to participate in this study.

What are my choices if I decide not to take part in this study?
Proceed with getting a high volume bowel preparation for cleansing prior to colonoscopy without being in a study.

If you take part in this study, what activities will be done only for research purposes?
Activities that are performed only for research purposes include:

- You will be randomized (flip of a coin) to use either MoviPrep or GoLYTELY for the bowel preparation for the procedure
- Administration of a questionnaire regarding the bowel preparation
- Scoring of bowel preparation quality by a gastroenterologist who is blinded to the bowel preparation you received
- We will collect information from your medical records about the colonoscopy and the duration of your hospitalization.

How will you keep my data safe and private?
We will keep information we collect about you confidential. We will share it with others if you agree to it or when we have to do it because U.S. or State law requires it. We have made careful plans to protect the identities of the people who are in the study and the confidentiality of the information collected about them for this study. The identities of the people who join this study will not be included in any scientific publications or presentations of the results.

Efforts will be made to protect the identities of the participants and the confidentiality of the research data used in this study. Participants will be given an ID. Data will be recorded on case report forms and entered into an electronic database for analysis. The database is called REDCap, which was developed specifically around HIPAA-Security guidelines to assure patient confidentiality and protect personal health information. We will not collect any personal identifying data, apart from procedure or event dates, such as date of colonoscopy or date of surgery. Data forms and the list of participant identification codes will be locked in a file cabinet in a locked office. All computers with research information are encrypted and password protected.

Your permission to use your health information for this study will not end until the study activities by the research team are completed. During this study, participants may not have access to the study data. You may request study data once the study activities have been completed.

Who may use or see your health information?
By signing this form, you are allowing the research team access to your medical records. If you do not allow use of your health information for this study, you may not participate in this study. The research team includes the researchers listed in this consent form and other personnel involved in this study at Yale New Haven Hospital and Bridgeport Hospital. The Principal Investigator Dr. Li will have access to your health information. You are also permitting any health care provider holding your health information needed for this study to give copies of it to the research team.

When we publish the results of the research or talk about it in conferences, we will not use your name. If we want to use your name, we would ask you for your permission.

We will also share information about you with other researchers for future research but we will not use your name or other identifiers. We will not ask you for any additional permission.

What Information Will You Collect About Me in this Study?

The information we are asking to use and share is called "Protected Health Information." It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission. If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to Yale Privacy Officer at 203-432-5919.

The specific information about you and your health that we will collect, use, and share includes:

- Research study records
- Medical and laboratory records of only those services provided in connection with this Study.
- The entire research record and any medical records held by ***Yale New Haven Hospital***.
- Records about your study visits
- Information obtained during this research regarding
    - Physical exams
    - Laboratory, x-ray, and other test results
    - Diaries and questionnaires

How will you use and share my information?

We will use your information to conduct the study described in this consent form.
We may share your information with:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University, the Yale Human Research Protection Program and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- The U.S. Food and Drug Administration (FDA) This is done so that the FDA can review information about MoviPrep and GoLYTELY involved in this research. The information may also be used to meet the reporting requirements of drug regulatory agencies.
- Health care providers who provide services to you in connection with this study.
- Laboratories and other individuals and organizations that analyze your health information in connection with this study, according to the study plan.
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team
- Others authorized to monitor the conduct of the Study

We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

What if you decide not to give permission to use and share your personal health information?

If you do not allow use of your health information for this study, you may not participate in this study. If you choose to stop taking part in this study, you may cancel permission for the use of your health information. You should let the study staff or the study doctor, Darrick Li, MD, PhD, know in writing that

you are cancelling your permission. Information collected for the study before your permission is cancelled will continue to be used in the research.

Why must I sign this document?

By signing this form, you will allow researchers to use and disclose your information described above for this research study. This is to ensure that the information related to this research is available to all parties who may need it for research purposes. You always have the right to review and copy your health information in your medical record.

What if I change my mind?

The authorization to use and disclose your health information collected during your participation in this study will never expire. However, you may withdraw or take away your permission at any time. You may withdraw your permission by telling the study staff or Darrick Li, MD, PhD in writing at Yale University, New Haven, CT 06520.

If you withdraw your permission, you will not be able to stay in this study but the care you get from your doctor outside this study will not change. No new health information identifying you will be gathered after the date you withdraw. Information that has already been collected may still be used and given to others until the end of the research study to ensure the integrity of the study and/or study oversight.

Participation is voluntary

It is up to you to decide whether or not to take part in this study. If you decide to take part, you may still withdraw at any time. If you do not wish to be in this study or leave the study early, you will not lose any benefits to which you are otherwise entitled. You must withdraw in writing in order to withdraw your permission for us to continue to collect and use further information. However, the information we already collected before your withdrawal will be used by investigators to complete the study and to record any information concerning the safety of any study-related method. If you do not take part in this study, you can still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctor or other staff and it will not affect the usual care that you receive as a patient.

Who will pay for treatment if I am injured or become ill due to participation in the study?

If you are injured while on study, seek treatment and contact the study doctor as soon as you are able.

Yale School of Medicine and Yale-New Haven Hospital do not provide funds for the treatment of research-related injury. If you are injured because of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available.

You do not give up any of your legal rights by signing this form.

Who can answer my questions about the study?

You can talk to your study doctor about any questions, concerns, or complaints you have about this study. Contact the study doctor, Darrick Li, MD, PhD at (203) 285-4506.

If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Investigation Committee at (203) 785-4688.

Authorization and Permission:

I have read (or someone has read to me) this form and have decided to participate in the project as described above. Its general purposes, the particulars of my involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

By signing this form, I give permission to the researchers to use and give out information about me for the purposes described in this form. By refusing to give permission, I understand that I will not be able to participate in this research.

Participant Printed Name	Participant Signature	Date
Legally Authorized Representative	Legally Authorized Representative Signature	Date
Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date

If after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at (203) 432-5919.

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator, Darrick Li, MD, PhD at (203) 285-4506. If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Investigation Committee at (203) 785-4688.