Protocol Title: Early Foley catheter removal after diverticular colovesical fistula repair

NCT # 05235204

Date: March 16, 2022

UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL
COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title: Early Foley catheter removal after diverticular colovesical fistula repair H00016345

IRB No.: H00016345

Sponsor: UMass Memorial Medical Center Department of Colorectal Surgery

Investigator: Dr. Karim Alavi

67 Belmont Street

Worcester, MA01605

Daytime Phone Number: 508-334-8195

24-Hour Phone Number: 508-334-8195.
A 24-hour answering service will be able to put you in contact with on-call colorectal surgeon.

You are being invited to take part in a research study. Someone will explain this research to you. This form helps to sum up their explanation.

In this form, "you" generally refers to the person who takes part in the research. If you are being asked as the legally authorized representative, parent, or guardian to allow someone else to take part, "you" in the rest of this form generally means that person.

KEY INFORMATION

You are being invited to participate in a research study because you have been referred to a colorectal surgeon for surgical repair of colovesical fistula.

If you have questions or don't understand something, please ask.

Taking part in this research is voluntary and completely up to you. You are free to say no or to leave the research at any time. There will be no penalties or changes in the quality of the health care you receive, and you will not lose any benefits to which you are otherwise entitled.

The main question this study is trying to answer is whether Foley catheter (urinary/bladder catheter) can safely be removed 2-3 days after surgical repair of colovesical fistula.

A mainstay of post-operative bladder management after colovesical fistula (CVF) repair is decompression with a Foley catheter. There is only limited data in the colorectal surgery literature addressing catheter management after CVF repair and no standard protocol which dictates the time period required for bladder drainage. There is no evidence to suggest prolonged catheterization has an advantage over early catheter removal. Similarly, there is no standard protocol at UMass with regard to post-operative bladder management. Based on our historical data the median time for catheterization is 9 days with a range from 2-35 days. Early catheter removal may benefit patients by allowing catheter removal prior to discharge from the hospital. This could eliminate the cost and inconvenience of outpatient management of a bladder catheter as well as decrease complication risks associated with prolonged catheterization. The goal of this study is to standardize a pathway for early catheter removal after colovesical fistula repair in eligible patients.

If you join this research, you will be assigned to the study group for early Foley catheter removal.

You will undergo your planned procedure and will return for routine follow-up appointments which will occur 1-3 weeks and 3-6 weeksafter your operation .If you do not participate in the study, you will be seen in the clinic using this same timelineWe will continue to collect information from your medical record for up to 30 days after your procedure. You will have no additional clinic visits required for this study that are not part of routine post-operative follow-up.

You may not want to be in this study if you are uncomfortable with:

- Sharing your private information with researchers
- Being tested for pregnancy

Risks:

There is a risk of post-operative urine leak and delayed diagnosis of urine leak. Complications of urine leak may include worsening abdominal or suprapubic pain (as you should expect to have some pain after surgery), infection, renal failure, sepsis, re-operation, or death. This risk of urine leak is estimated to be low. Additionally, Foley catheter will not be removed if there is a positive leak test at the end of the operation or if the post-operative cystogram shows evidence of urine leak. The risk of delayed diagnosis of urine leak is expected to be low because urine leak usually presents with a constellation of symptoms that prompt urgent evaluation and are easily diagnosed with lab results and radiologic studies. These complications may pose risks that are

currently unforeseeable. These complications may pose risks to an embryo or fetus should the subject be pregnant, or become pregnant.

Risk of radiation exposure. There will be risk of radiation exposure because you will undergo an x-ray cystogram prior to Foley catheter removal. Currently, patients who undergo colovesical fistula repair normally have cystogram performed prior to Foley catheter removal as part of standard practice. For this reason, there will be no additional risk of radiation in the study group compared to standard practice. Exposure to radiation and fluoroscopic dye may pose risks that are currently unforeseeable. Radiation and fluoroscopic dye exposure may pose risks to an embryo or fetus should the subject be pregnant, or become pregnant. The risk of radiation exposure is not anticipated to be any higher than standard management which also includes cystogram prior to Foley catheter removal.

As part of this study, we will be collecting personal information. There is a risk that your information could be lost or seen by people who should not have access to it. This is very unlikely to happen, and we will take steps to protect your information.

There may also be risks that we do not know yet.

Benefits: Participants may benefit from early removal of Foley catheter in the post-operative period and avoidance of outpatient Foley catheter management.

We cannot promise that your Foley catheter will be removed early if you take part in this research as this will depend on the results of your cystogram study. Your participation will help us to gain knowledge that may help decrease average days of indwelling Foley catheter in patients undergoing colovesical fistula repair, as well as associated inconvenience and cost of outpatient management of the catheter.

Alternatives: If you choose not to participate in this study, you will receive standard post-operative management of Foley catheter which is at the discretion of your surgeon. Typically, Foley catheter is left in place for up to 7 days or longer and cystogram is performed prior to removal of Foley catheter.

This research is not designed to diagnose, treat, or prevent any disease. Your alternative is to not take part in the research.

Conflict of Interest: There are no conflicts of interest to disclose.

If you think you might like to participate in this research, please continue reading to learn more about the details of this study.

STUDY DETAILS

How many people will take part in this research?

We expect to enroll 48 subjects at UMass Memorial Health Care.

What happens if I say yes, I want to be in this research?

If you decide to participate in this study you will have an x-ray cystogram performed on the second or third day after your operation. If this study shows no evidence of urine leak then your

Foley catheter will be removed. If there is evidence of urine leak, then you will not be eligible for early catheter removal and your Foley catheter will be managed at the discretion of the surgeon. No changes will be made to normal pre-operative evaluation, surgical procedure, or follow-up visits. Your follow-up appointments will occur 1-3 weeks and 3-6 weeks post-operatively and will occur on the same timeline as if you do not participate in the study. At the time of follow-up visit we will collect information on your surgical outcomes and document any post-operative complications.

Will you be collecting any specimens from me?

No

Will it cost me any money to take part in this research?

You or your insurance will be billed for all routine medical and diagnostic costs that are part of the standard of care for treating your condition. This may include the cost of tests, procedures, or medicines to manage any side effects. You will be responsible for any deductibles, co-payments, or co-insurance payments that your coverage normally requires.

Will I be given any money or other compensation for being in this study?

You will not be paid for taking part in this research.

At this time, we do not think that the results of the research will lead to commercial profit. In the event it does, there are no plans to share profits with you.

What happens to information about me?

We will limit access to your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete privacy. The Sponsor, UMMS Institutional Review Board (the committee that reviews, approves, and monitors research on human subjects) and other representatives of UMMS may need to review your records. As a result, they may see your name, but they are trained to keep information confidential. Your identity will remain confidential in any study results that are made public.

If we learn that you plan to hurt yourself or others, we will break confidentiality to help you.

If we learn of any child or elder abuse, we are required to break confidentiality and report this to state authorities.

What happens if I am injured because I took part in this research?

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

The University of Massachusetts Medical School does not provide funds for the treatment of research-related injury. If you are injured as a result 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.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to:

- Follow the directions of the study doctor and research staff.
- Tell your study doctor and staff about all of your health issues.
- Promptly report any symptoms such as fever, abdominal pain, pain with urination, or difficulty with urination after your Foley catheter is removed and/or you are discharged from the hospital.

What happens if I say yes, but I change my mind later?

You are free to leave the study at any time. There are no penalties and you do not lose any benefits to which you are otherwise entitled. Data that we have already used will stay in the study database and cannot be removed in order to maintain the integrity of the research.

If you decide to leave this research, contact the research team so that the investigator can remove you from the study protocol.

If you decide to stop, we may ask if we can contact you for safety reasons or to follow your health. We may also ask you if we can collect data from your medical records and your routine medical care.

Can I be removed from the research without my approval?

The person in charge of this research study can remove you even if you want to continue. This may happen if your pre-operative evaluation reveals that you do not meet study inclusion criteria. You will not be eligible for early Foley catheter removal if there is evidence of urine leak at completion of your procedure or if there is evidence of urine leak on post-operative cystogram. Your data will still be collected even if you are not eligible for early Foley catheter removal.

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

How will my information be stored and when will it be destroyed?

We will remove your name and any other information that could directly identify you from your data. We will replace this information with a code number. We will create a master list linking your code number to your medical record number. We will keep this list separate from your data.

We will keep paper documents under lock and key. We will keep electronic health information and research data on secure computer networks. These computer networks have many levels of protection.

There is no limit on the length of time we will store your deidentified data. We will destroy the master list of identifiers when the study has concluded and all data analysis has been performed. We expect this to occur on or before 05/31/23.

We will not use or share your data for any future research unrelated to this study, even if identifiers are removed.

Who has access to my information?

Signing this document means you allow us, the researchers in this study, and others working with us to use some protected health information for this research study.

As part of the research, UMass Memorial Medical Center or any other healthcare facility where you are treated may disclose the following information:

- Demographic and identifying information like your name, date of birth, address, telephone number, and your email address
- Related medical information like family medical history, and current and past medications or therapies
- Information from physical examinations, such as blood pressure reading, heart rate, temperature, height/weight, and lab results
- All tests and procedures that will be done in the study

In the event you die while enrolled in the study, all medical records related to your treatment and death at any healthcare facility will be released to Dr. Karim Alavi and their research staff.

Your health information and research records will be shared with the study team and with individuals and organizations that conduct or watch over this research, in order to conduct the study and to make sure it is conducted as described in this form. Information and records may be shared with:

- The Institutional Review Board (IRB) that reviewed this research
- UMass Memorial Medical Health Care and the University of Massachusetts Medical School, including their Institutional Review Board (IRB) and research, billing, and compliance offices

We will protect your identifiable information from disclosure to others to the extent required by law, but we cannot promise complete secrecy.

We are legally required to disclose information about child abuse, abuse of the elderly or disabled, you potentially harming yourself or others, and certain reportable diseases.

Any disclosure carries the potential for re-disclosure. Once your protected health information is disclosed, it may no longer be protected by federal privacy laws.

Your authorization does not have an expiration date. If you change your mind, you have the right to revoke your authorization in writing or using the contact information at the beginning of this form. In such a case, you will not be allowed to continue to participate in the study. We will not collect any new information and may only use the information already collected for this research study. Your information may still be used and disclosed if you have an adverse event.

You do not have sign this authorization. If you choose not to sign, it will not affect your treatment, payment, or enrollment in any health plans, or affect your eligibility for benefits. You will not be allowed to participate in the research study.

If you could get pregnant, you will have pregnancy testing as part of this study. Only you will be told the results. A positive pregnancy test means that you cannot be in this study. If you are uncomfortable with pregnancy testing, then you should not be in this study.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Will you share any results with me?

Your personal test and study results will be shared with you.

It may be several years before the results of the research are available. If you would like us to try to reach you at that time, please let us know. We will ask for your contact information.

Who can I talk to?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed on the first page.

This research is being overseen by an Institutional Review Board. An IRB is a group of people who perform independent review of research studies. You may talk to them at (508) 856-4261 or irb@umassmed.edu for any of the following:

Your questions, concerns, or complaints are not being answered by the research team.

You cannot reach the research team.

You want to talk to someone besides the research team.

You have questions about your rights as a research participant.

You want to get information or provide input about this research.

Your signature documents your consent to take part in this research.

Signature of adult research participant	Date
Printed name of adult research participant*	

**If signed by legal representative, please explain relationship to patient and legal representative's authority to act for patient:*

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Signature of person obtaining consent	Date
Printed name of person obtaining consent	