MedStar Health
Research Institute

Permission to Take Part in a Human Research Study

Title of research study: **Intravesical Lactobacillus (LGG®) to Reduce Urinary Symptoms After Spinal Cord Injury-AIM 2**

Investigator: Suzanne Groah, MD, MSPH

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you have a Spinal Cord Injury, Multiple Sclerosis, or Spina Bifida and use an intermittent catheter.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The purpose of this study is to determine the best dose of intravesical *Lactobacillus (LGG ®)* a probiotic (healthy bacteria) to be used to reduce urinary symptoms.

How long will the research last and what will I need to do?

We expect that you will be in this research study until you have completed either 2 or 4 doses of *LGG®*.

You will be asked to complete questionnaires at the initial assessment, and then you will be put into a high or low dose group. When experiencing urinary symptoms, specifically "trigger symptoms" ('cloudy' or 'bad-smelling, stronger, fouler' or more pungent than normal), you will instill *LGG®* through your catheter either 2 (~24 hours) or 4 (~48 hours) times. For subjects that are local, urine samples will be collected before and after the intervention procedure. Subjects will remain in the study until they have completed either 2 or 4 doses of *LGG®* or up to 29 months.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be part of this research?"***

Is there any way being in this study could be bad for me?

If you decide to participate in this study, you should know there may be risks. You should discuss these with the investigator and your regular doctor and you are encouraged to speak with your family and friends about any potential risks before deciding. Potential risks and side effects related to this study include:

- Discomfort from catherization and instillation of *LGG*®
- Emotional discomfort from answering questions
- Stomach infection due to *LGG*®
- *LGG*® causing Urinary tract infection (UTI) or urinary symptoms

Please tell the investigator about all medications including over-the-counter drugs or herbal supplements you are taking, even if you don't think they are important. Only you can take the study drug *LGG*®. Do not share it with anyone else. It must be kept out of reach of children and persons who may not be able to read or understand the label. There may also be risks and side effects other than those listed above that we cannot predict Many side effects go away in a short time after the *LGG*® is stopped, but, in some cases, side effects can be serious, long lasting and/or life threatening. If you have any unwanted side effects, you should ask the investigator whether there are any medications or other things that may be done to make the side effect less uncomfortable.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

We cannot promise any benefits to you or others taking part in this research. However, possible benefits include improvement in your urinary symptoms when using *LGG*®.

Regardless of your personal results or experience during this study, your participation in this research will help further development to determine the effect and best dosage of *LGG*® to address urinary symptoms.

What happens if I do not want to be part of this research?

Participation in research is completely voluntary. You can decide to participate or not to participate. Your alternative to participating in this research study is to not participate.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at Amanda.k.rounds@medstar.net@medstar.net (202-877-1591)

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (301) 560-2912 or MHRI-ORIHelpDesk@medstar.net if:

- 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.

How many people will be studied?

We expect about 182 people here will be in this research study out of 182 people in the entire study nationally. Of those 182, at least 68 will be recruited locally for urine collection

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

Eligibility Screening
Before participating inclusion/exclusion will be assessed to determine eligibility.

Initial Assessment
Upon consent, you will complete several questionnaires including demographics, medical history, bladder management, current medications, and current urinary symptoms.

	Day 0	Weekly until instillation	Before Instillation	After Instillation
Screening	X			
Informed Consent	X			
Questionnaires	X			
Urinary symptoms questionnaire	X	X	X	X
Give 1st urine sample (If local participant)			X	
Give 2nd Urine Sample (If local participant)				X

Randomization

After initial assessment you will be put into the low or high dose group. The low dose will do 2 doses of *LGG*® in 24 hours. The high dose will do 4 doses of *LGG*® in 48 hours when experiencing urinary symptoms. The dosage group ("Low" vs. "High") you are assigned to will be chosen by chance, like

flipping a coin. Neither you nor the study doctor will choose what dosage you get. You will have equal chance of being given either dosage.

Urine Samples (*Local participants only***)**

We will collect 2 urine samples (24-48 hours before instillation and 24-48 hours after last instillation). In addition to completing the urinary symptoms questionnaire prior to urine collection, participants will complete the urinary symptoms questionnaire after second urine collection (following instillation) and 3 days after final urine collection for a total of 3 times.

Initial Urine Collection: Urine will be collected by study staff in your own home or at the study site, per your preference. You will use a new intermittent catheter. You will complete the symptoms questionnaire as a confirmation of symptoms at the time of urine collection.

Repeat Assessment: You will be scheduled for a repeat urine collection after your last instillation. This assessment will mirror the initial urine collection described above.

****LOCAL PARTICIPANTS ONLY****

If local to DC Metropolitan area are you interesting in participating in urine collection (includes urine sample before first instillation and after the last instillation)?

□Yes **□No**

If yes, we would like to save and store a small amount of urine at Children's National Medical Center (CNMC) for up to 10 years. This sample could be used for potential future research on urinary symptoms. Only study approved staff will have access to the specimens

Do you agree to have this small amount of urine collected and saved for up to 10 years?

□Yes **□No**

Intervention training

You will receive a training manual (hard copy and/or electronic) for details on how to complete the *LGG*® instillation, and number of instillations and duration for your group (low or high). You will be given a manual (hard copy or electronic) and will participate in a 1-on-1 training session with our Consumer Expert.

You will complete the Urinary Symptom Questionnaire weekly until study completion.

Intervention

For the *LGG*® instillation, you will be instructed to mix the contents of 1 *LGG*® capsule into sterile saline. After mixing, you will draw up the liquid mixture into a syringe and instill through the intermittent catheter. You will receive 2 or 4 *LGG*® capsules (depending on randomization group) for the instillation intervention. Two additional capsules will be provided to each group – one of these additional capsules capsule will be used for training and one capsule will be a back-up in the event a capsule breaks during the preparation process. Therefore, you will receive 4 (low dose) or 6 (high dose) LGG capsules in your kits but will only instill 2 or 4 LGG capsules as instructed using the self-management protocol for probiotic (SMP-PRO). Any unused capsules will be returned to the study coordinator at the end of the participant's participation. You will remain in the study for up to 29 months, with participation ending after one completed intervention (either 2 or 4 doses) and post-intervention assessments are complete. If urinary symptoms do not occur during the 29 months, participants will be asked to return any remaining capsules. The Project Coordinator or RA will count (and collect, if necessary) any unused capsules to maintain counts.

You will complete the Urinary Symptom Questionnaire daily for 4 days (during and post instillation).

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

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

- Complete initial assessments
- Weekly urinary symptoms questionnaire reporting until study completion
- Completing training with consumer expert on how and when to instill *LGG*®
- Instill *LGG*® as instructed per training manual
- Contact research team when instillation occurs
- Complete urinary symptoms questionnaire 4 consecutive days (during and post instillation)
- **If Local** contact research team to set up urine collection before instillation and after instillation occurs

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

You can leave the research at any time and it will not be held against you.

If you decide to leave the research, no adverse consequences will occur. If you decide to leave the research study, contact the investigator so that the investigator can collect unused LGG®.

If you stop being in the research study, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

Is there any way being in this study could be bad for me? (Detailed Risks)

- Discomfort from catherization and instillation of intravesical *LGG*®
- Emotional discomfort from answering questions
- Urinary tract infection (UTI) or urinary symptoms due to *LGG*®

In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

You and your insurance company will be charged for the health care services that you would ordinarily have to pay for. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will have to pay for yourself.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. Your records of being in this study will be kept private except when ordered by law. The following people will have access to your study records:

- The investigator and research staff
- The United States Food and Drug Administration (FDA)
- Department of Defense (DOD)

Your personal health information (PHI) will be kept private to the extent allowed by the law. Study records identifying you will be kept confidential and will not be made publicly available.

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent. If the sponsor pays any of your medical expenses, we may be required to give the sponsor your name, date of birth, and Medicare ID or social security number.

A description of this clinical trial is available on http://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.

Federal law provides additional protections of your medical records and related health information. These are described in an attached document.

HIPAA Authorization

We are committed to respecting your privacy and to keeping your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information including the health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. The health information we may collect from you and use for this research includes:

- Medical history
- List of medications
- Lab tests, or certain health information indicating or relating to a particular condition as well as diaries and questionnaires
- Records about study medication or drugs

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of MedStar Health and its clinical partners (or affiliates): the MedStar Health Research Institute Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or MedStar Health policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the MedStar Health workforce, who may need to see your information, such as administrative staff members from the MedStar Health Research Institute, Office for Research Integrity and members of the Institutional Review Board.
- Laboratories and other individuals and organizations that may need to see your health information in connection with this study.
- Other MedStar Health research centers and MedStar Health contractors who are also working on the study.
- Study monitors and auditors who make sure that the study is being done properly,
- Department of Defense (DOD), who is sponsoring the study, and that company's contractors and partners.
- Children's National Medical Center
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those people may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will expire at the end of research project.

After the expiration date, MedStar Health may not gather new information about you, or use or disclose your personal health information collected in this study for any purpose other than the research study described in this consent unless MedStar Health obtains permission to do so from you.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

PI's Name: Suzanne Groah, MD, MSPH
Institution: MedStar National Rehabilitation Hospital
Department: Research
Address: 102 Irving St NW,
Washington, DC 20010

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study if you do not allow this. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

Can I be removed from the research without my consent?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include any adverse effects due to an LGG® instillation or if new information becomes available that alters the risk-benefit ratio relative to your participation. We will tell you about any new information that may affect your health, welfare, or choice to stay in the research study.

What else do I need to know?

This research is being funded by Department of Defense (DOD).

If you need medical care because of taking part in this research study, contact the investigator and medical care will be made available. Generally, this care will be billed to you, your insurance, or other third party. MedStar Health has no program to pay for medical care for a research-related injury. If you feel that you are having a medical emergency, you should go to the emergency room right away.

Instead of being in this research study, your choices may include: Not to be a part of this study the important risks and possible benefits of these alternatives include: There are no risks or potential benefits not to be a part of this study.

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers will contact you to let you know what they have found. If the researchers return genetic test results to you, it may be because they think you could have a health risk and want to recommend that the test should be re-done by a certified clinical laboratory to check the results. If this happens, then you may want to get a second test from a certified clinical laboratory, consult your own doctor, or get professional genetic counseling. You may have to pay for those additional services yourself.Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	IRB Approval Date

Signature Block for Capable Adult