

Probiotic *Lactobacillus* is safe and well tolerated when instilled in the bladder

Article Title: Intravesical *Lactobacillus rhamnosus* GG is safe and well tolerated in adults and children with neurogenic lower urinary tract dysfunction: first-in-human trial



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Key points:

- There are bacteria that reside in urine and healthy bladders (this is termed the healthy urobiome).
- *Lactobacillus* is a type of bacteria that is considered to be a “probiotic” or beneficial to health.
- People with neurogenic lower urinary tract dysfunction (NLUTD) (neurogenic bladder) have less or even no probiotic *Lactobacillus* in their bladders and this may contribute to urinary symptoms and urinary tract infection.
- This study evaluated the safety and tolerability of instilling a probiotic, *Lactobacillus rhamnosus* GG (LGG), directly into the bladder using the bladder catheter in individuals with neurogenic bladder.
- When participants experienced cloudy or more foul-smelling urine, they mixed LGG with normal saline and instilled the mixture into the bladder using their bladder catheter.
- Doing this was found to be safe and well-tolerated.

Plain language summary:

Urinary tract infections (UTIs) are the most common outpatient infections worldwide, and people with NLUTD/Neurogenic Bladder (NB) are at highest risk. It is commonly accepted that UTI is over-diagnosed, leading to over-treatment with antibiotics. There is a great need for an approach to suspected UTI that does not involve antibiotics.

In 2012, our research team discovered that not only do bacteria reside in the bladder under healthy conditions, but we found that people with NB due to SCI/D have less “probiotic” (or beneficial) *Lactobacillus* in their bladders than people without NB. Our team developed a protocol in which the probiotic, *Lactobacillus rhamnosus* GG (LGG®), is mixed with normal saline and instilled directly into the bladder using the bladder catheter. The ultimate goal was to reduce bothersome symptoms and restore beneficial bacteria to the bladder.

This study was the first of its kind in humans and aimed to evaluate the safety and tolerability of the probiotic (LGG, also

called a live biotherapeutic) instilled into the bladder using a bladder catheter in individuals with neurogenic bladder. When urine became cloudier or developed a more unpleasant odor, participants self-administered LGG into the bladder, as these symptoms might represent a pre-UTI state.

Throughout the trial, the researchers closely monitored the participants to determine if any significant side effects or harm was caused by LGG. The findings revealed that intravesical (“in the bladder”) LGG was well-tolerated. There were no major adverse events or significant side effects reported during the study period that were felt to be due to the probiotic.

In conclusion, this study provided valuable insights into the safety and tolerability of self-administered intravesical LGG for individuals with neurogenic bladder who experienced cloudy or foul-smelling urine. The study was not designed to conclude whether LGG improved urinary symptoms but provides evidence to pursue larger studies, now underway, to determine whether LGG can help reduce urinary symptoms.

Keywords and acronyms:

- **Intravesical:** Relating to the inside of the bladder.
- ***Lactobacillus rhamnosus* GG (LGG):** A specific strain of bacteria often used as a probiotic.
- **Instill:** Put a liquid into something
- **Neurogenic Lower Urinary Tract Dysfunction (NLUTD)/ Neurogenic Bladder (NB):** A condition where the nerves that control the bladder are damaged or not working well. This can cause problems with controlling when and how much you urinate.

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