



PRESS RELEASE

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Nature Microbiology publishes the paper “Targeted innate immune inhibition therapy compared with antibiotics for recurrent acute cystitis: a randomized, open-label phase 2 trial.”

This groundbreaking study introduces an entirely new approach to managing recurrent urinary tract infections. Instead of killing the bacteria, the treatment focuses on targeting and calming the disease response. Clinical efficacy of this approach is demonstrated in this study, showing effects comparable to standard antibiotic therapy. This discovery could also mark a major breakthrough in the fight against antibiotic resistance and the future treatment of infections.

This non-antibiotic treatment approach is conceptually novel and the study is the first to demonstrate clinical effects comparable to antibiotics in this patient group, explaining why a leading international journal such as *Nature Microbiology* has agreed to publish <https://www.nature.com/articles/s41564-026-02262-1>. Scientists collaborating with Hamlet BioPharma have also developed several new therapeutics against bacterial infections with potent effects. These new discoveries suggest a transformative shift in infectious disease management, built on the discovery of molecules that target the disease response of the host rather than the bacteria. These treatments are promising tools in the fight against antibiotic resistance and essential to innovate the treatment of bacterial infections.

The study compared the treatment efficacy of the IL-1 receptor antagonist anakinra to the antibiotic nitrofurantoin, showing similar efficacy of both treatment approaches in patients with recurrent acute cystitis. Female patients with a documented history of recurrent cystitis and a current acute cystitis episode, were randomized to treatment with anakinra or nitrofurantoin for five days. Primary and secondary efficacy end points were reached, defined as the reduction in typical symptoms, measured by the acute cystitis symptom score (day 5), longitudinal symptom scores, recurrence rates, quality of life, and microbiology and gene expression analysis at follow-up on days 15, 30 and at six months. Symptom scores were decreased in the anakinra ($P<0.001$), and nitrofurantoin ($P<0.001$) arms after five days and remained low after 15, 30 days and 6 months. Recurrences were less frequent after 6 months in both treatment groups compared to the 6-month pre-enrolment history ($P<0.001$ for anakinra and $P=0.004$ for nitrofurantoin) and the quality of life was increased. Immune gene

expression was inhibited in the anakinra treated patients but not in the nitrofurantoin group and the microbial burden was affected in both groups.

The main goal of antibiotic therapy is to remove bacteria and end the disease process that they provoke. Since the discovery of antibiotics, bacterial infections have been treated with great success, and treatment still relies on antibiotics with clinical efficacy. The rise in antibiotic-resistance limits the therapeutic options, increasing mortality rates and the need for advanced medical care. Resistance to antibacterial drugs is particularly in common infections such as urinary tract infections (UTIs), highlighting the need for alternative therapeutic strategies. Hamlet BioPharma's phase 2 clinical trial in patients with recurrent acute cystitis offers a new solution to addressing this problem.

"This study was based on extensive molecular studies and preclinical treatment data from infection models, confirming the potential of this approach. The extensive data sets and advanced technology are unique, internationally, says Ines Ambite, PhD, Lund University.

"These findings create optimism in times when antibiotic resistance is a very dark cloud above all of our heads. The new treatments are also effective against antibiotic resistant bacteria", says Catharina Svanborg, Professor at Lund University, Founder and chairman of Hamlet BioPharma.

"Clinical studies like this are essential to validate new treatment concepts and drive the development towards the market. This next generation translational trial design is very important to further develop the field of UTI research," says Florian Wagenlehner, Professor at the University of Giessen, Germany.

Links to the publication: <https://www.nature.com/articles/s41564-026-02262-1>

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For further information, please contact

Ines Ambite, PhD, +46-762 08 89 58. Ines.Ambite@med.lu.se,

Catharina Svanborg, Chairman of the Board, Hamlet BioPharma AB, +46 709 42 65 49,

catharina.svanborg@hamlepharma.com