

Positive Phase II study shows similar clinical outcomes of immunotherapy and antibiotic treatment for recurrent acute cystitis, potentially reducing the need for antibiotics

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Hamlet BioPharma - the pharmaceutical company with a strong portfolio of projects for the treatment of cancer and infections - has successfully completed a controlled Phase II clinical trial in patients with recurrent acute cystitis (severe repeated infections of the urinary tract). The company now announces the outcome of a randomized Phase II study where patients were allocated to antibiotic treatment or anakinra, which is an Interleukin1 (IL-1) receptor antagonist (IL-1RA). The results show that most of the patients respond positively to the treatments and that the two treatments, immunotherapy and antibiotics, had similar outcomes. This was defined by a significant reduction in symptoms short term and long-term, a lower number of symptomatic recurrences than before the study and an increase in the quality of life.

Hamlet BioPharma is investigating alternative ways of treating bacterial infections by strengthening an individual's antibacterial defense with immunotherapy, thus bypassing the need for antibiotic use. Immunotherapy has the potential to reduce the need for antibiotics in this large patient group and potentially the threat of antibiotic resistance. Now we have clinical evidence supporting the benefits of immunotherapy against recurrent acute cystitis; a very common bacterial infection. Urinary tract infections are among the most prevalent infectious diseases globally, especially acute cystitis, which affects around 50% of all women during their lifetime and many of these women develop recurrent infections.

The anakinra study of recurrent cystitis is conducted in collaboration with the University of Giessen, Germany. It is the first of its kind to evaluate a targeted immunomodulatory approach in this 'very difficult to treat' patient population.

Non-antibiotic treatment strategies are increasingly needed to relieve patients of symptoms while preserving a healthy microbiome. A targeted immunomodulatory approach could potentially support the host, by driving the immune response away from inflammation, thereby removing or attenuating the debilitating symptoms. A more extensive analysis of the study outcomes will be submitted for publication.

"The results illustrate the strong potential of IL-1RA treatment for this important disease," says Florian Wagenlehner, Professor of Urology, University of Giessen.

"The clinical results confirm our extensive molecular studies, identifying IL-1 and IL-1RA as essential regulators of acute cystitis", says Ines Ambite, PhD, Project manager Hamlet BioPharma.

Infections caused by antibiotic resistant strains are difficult to treat and pose a great global health threat. The World Health Organization has declared infections caused by resistant strains to be one of the 'biggest threats to global health, food security and development today' and has highlighted the need to combat it with novel solutions. Immunotherapy offers a new approach to treating infections without antibiotics, with the potential to also benefit patients infected with antibiotic resistant strains.

For more information, please contact

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