

**The clinical trial of cell therapy developed by CZECRIN infrastructure for patients with "butterfly children" disease is ongoing at Brno University Hospital**

**An academic clinical trial for patients with the rare congenital disease epidermolysis bullosa (EB), also known as "butterfly children" disease, has been initiated in collaboration between the CZECRIN infrastructure (MU Faculty of Medicine) and the University Hospital Brno. The clinical trial aims to test the drug's safety and obtain the first information on how the cell therapy administered promotes the healing of chronic wounds.**

A team of doctors and nurses is conducting the clinical trial from the Burns and Plastic Surgery Clinic of the Brno University Hospital and the EB Centre at the Children's Dermatology Department of the Paediatric Clinic of the Brno University Hospital. In mid-October 2022, the drug was given to the first patient. After the necessary 24-hour observation, the man was discharged home from the hospital in good condition and will have regular follow-ups and repeat applications. He will be monitored in the study for one year. Three more patients will begin the treatment by the end of 2022 and early 2023. An initial safety analysis of the treatment will take place, and if the results are favourable, additional patients will be included in the study.

The cell therapy drug consists of mesenchymal stromal cells (MSCs). These cells in the human body help repair damaged structures and regulate the exaggerated functions of the immune system. According to existing research, MSCs have healing potential in acute and chronic wounds of various origins. Experts from the Advanced Cell Immunotherapy Unit (ACIU) at the Institute of Pharmacology of the Faculty of Medicine (MUNI) have been working on the development of the product for several years, preparing the MSC medicine from fat tissue of healthy volunteers in a "clean room" (GMP) environment.

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## Epidermolysis bullosa

Epidermolysis bullosa is a genetic disease caused by changes (mutations) in genes for specific connective tissue proteins. As a result of the mutations, the cohesion of the different layers of the skin, mucous membranes and internal organs is disturbed. Causal treatment is not available; patient care is mainly focused on caring for very fragile skin, keeping wounds clean, promoting healing and preventing infection.

## ACIU

The ACIU is part of the Institute of Pharmacology of the Faculty of Medicine of Masaryk University and operates under the Good Manufacturing Practice (GMP) regime. The unit has clean rooms for the production of cell therapy medicines and is regularly inspected by the State Institute for Drug Control. In cell therapy research and development projects, the ACIU cooperates intensively with the Transfusion and Tissue Department, the Department of Clinical Microbiology and Immunology of the Institute of Laboratory Medicine and clinical departments of the University Hospital Brno.

## CZECRIN

**CZECRIN** is the Czech national research infrastructure supporting academic clinical trials, which connects teaching hospitals, universities and scientific centres in the field of biomedicine. It is the Czech national hub of the European Consortium of Clinical Research Infrastructures (ECRIN-ERIC). Their common goal is to support the development of academic clinical trials and to improve cooperation at the national and international levels. CZECRIN currently conducts more than 25 national and international academic clinical trials in many areas, including paediatrics and rare diseases.



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