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Opportunity for children with hepatitis C. Most patients are already free of the virus after just one month of taking the drug

Researchers in Warsaw are looking for new therapeutic methods for children with chronic hepatitis C.

In 2010, The World Health Organization (WHO) recognized viral hepatitis (Hepatitis) as one of the greatest epidemiological threats of the 21st century, establishing July 28 as World Hepatitis Day.

Viral hepatitis poses a public health challenge. Approximately 1.4 million people worldwide die each year from hepatitis and the complications of the infection - cirrhosis or cancer. Unfortunately, less than 5% of those infected know about their disease.

The liver is the largest and one of the most important organs with a very high regenerative capacity. It participates in many processes in the body, including carbohydrate, protein and fat metabolism; synthesizes proteins, enzymes, lipids and lipoproteins, blood clotting factors, stores vitamins A, B12, D and iron and copper, detoxifies the body and supports immunity.

The etiological agents of viral hepatitis are viruses that exhibit hepatotropic properties. In Poland, infections with virus types A, B and C (HAV, HBV, HCV) are most common, with viruses D, E and G (HDV, HEV, HGV) far less common.

Opportunity for the youngest

Children are most often infected with hepatitis C virus from sick mothers. It is a progressive liver disease leading to cirrhosis of the organ and hepatocellular carcinoma. In children, it is usually described as a benign disease, but researchers' observations indicate that the percentage of children who develop advanced fibrosis, including cirrhosis, before reaching adulthood reaches several percent. In the case of smear-acquired infection, advanced liver disease can occur at a younger age compared to children infected later in life. Effective antiviral treatment in children with chronic hepatitis C can prevent the development of end-stage liver disease, cirrhosis and hepatocellular carcinoma in young adults.

- A non-commercial ABM-funded clinical trial titled "Treatment of children aged 6 - 18 years with chronic hepatitis C with a pangenotypic drug with direct antiviral activity (sofosbuvir/welpatasvir)," which is being conducted by Warsaw Medical University and the Provincial Hospital for Infectious Diseases in Warsaw, offers a real chance for therapy

in children infected with all genotypes of the virus, regardless of the degree of liver fibrosis. Most patients are already free of the virus after just one month of taking the drug. We hope that all patients will be cured and permanently eliminate the disease, and will enter adulthood as healthy people without medical burdens," explains Maria Pokorska-Spiewak, MD, principal investigator.

Currently, the best therapeutic option in chronic hepatitis C in children, allowing complete eradication of the virus from the body, are - according to current European and Polish recommendations - non-interferon therapies based on the use of direct acting antivirals (DAAs). DAAs are drugs with very high efficacy (above 95%), ease of administration (orally), short duration of therapy (usually 12 weeks) and a good safety profile compared to interferon therapies previously available for children.

Children are ideal patients for treatment with DAAs. They tend to have less advanced liver disease, are less likely to develop extrahepatic manifestations of the disease, and less likely to have comorbidities requiring the use of drugs that could potentially interact with DAAs. Meanwhile, of the approximately ten drug combinations registered in adults, only a single one can be used in children in Europe. Moreover, the Ministry of Health's current Therapeutic Programs in Poland do not provide for the possibility of treating children with modern non-interferon therapies based on DAAs.

- During the first visit to the Clinic, we get to know the patient and his parents, talk at length to clarify any doubts the parents and the patient have about the study, and then obtain the informed consent of the patient and parents to participate in the study, analyze the previous medical history, take tests to see at what stage the disease is and what the state of the child's liver is. Each patient then reports to the Clinic once a month, where he or she is examined and given medication for the next month of therapy. At any time, 24 hours a day and seven days a week, parents can contact us by phone if any problems arise. Fortunately, there are not many such situations, because the treatment is perfectly tolerated by the children," explains Maria Pokorska-Spiewak, MD, principal investigator.

Until now, children in Poland have had limited access to modern therapies based on DAAs mainly within the framework of commercial clinical trials, which excluded the possibility of treating patients burdened by concomitant diseases (e.g., with HIV co-infection) or severe liver disease. The price of these drugs (tens of thousands of zlotys for a month's therapy) precludes patients from purchasing the

preparations on their own.

- Recruitment for the study is now closed. Due to the very high interest in the study among patients and their parents, we were able to recruit the planned 50 patients very quickly. All the children have already started the 3-month treatment, more than half have even completed it. In August, visits will begin to confirm the effectiveness of the treatment. Its definition is the absence of detectable virus in the body 3 months after the end of treatment," concludes Dr. Maria Pokorska-Spiewak, principal investigator.

[Previous Page](#)

[Next Page](#)