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Fund "Nauka" Project N_2 21014 Resume – Competitive-based Session 2021:

"Monitoring of hepatitis B antiviral therapy"

Project leader: assoc. prof. Irina Ivanova Ivanova, MD, PhD

The aim of this project is modern evaluation of the effectiveness of antiviral treatment against hepatitis B virus (HBV). Within 3 years 70 patients with chronic hepatitis B or liver cirrhosis on long-term nucleoside/ nucleotide treatment from the hepatological register of the Clinic of Gastroenterology will be followed up. The indications for treatment will correspond to the Consensus of the Bulgarian Gastroenterological Society: biochemical activity and/ or liver damage proven by liver biopsy. At onset, at 6, 12, and 24 months of treatment with Tenofovir or Entecavir within 4 main visits, routine clinical evaluation, liver enzymes, abdominal ultrasound, HBeAg status, and viral load will be expanded with the inclusion of two new serological markers of HBV activity: quantification of hepatitis B virus surface antigen (HBsAg) and "cor"-bound antigens (HBcrAg). The dynamics of these viral proteins is expected to categorize patients with viral suppression into two main groups: with and without a significant reduction in HBV translational activity. Additional tasks will be determining baseline factors for a favorable response to antiviral therapy and vice versa, predictors of disease progression and risk of hepatocellular carcinoma, despite regular antiviral therapy. The tendency of decreasing the production and secretion of HBsAg and HBcrAg is likely to be a future indicator of treatment discontinuation in some patients with hepatitis B, without risk of recurrence, with the possibility of post-therapeutic immunological control. This approach would reduce the severity of long-term antiviral therapy and the risk of its side effects, and would indicate more aggressive monitoring and follow-up of patients with suboptimal responses.