EFFICACY OF HUMAN RECOMBINANT INTERLEUKIN-2 (RONCOLEUKIN®) IN TREATMENT OF SEVERE NEONATAL BACTERIAL INFECTIONS COMPLICATED WITH LYMPHOPENIA

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**Brief introduction:** Lymphopenic episodes which develop during severe neonatal infections are sings of immune deficiency and predictors of lethal outcome.

Human recombinant interleukin-2 preparation (Roncoleukin<sup>®</sup>, (hrIL-2)) can be used in such cases to improve lymphocyte activation, proliferation, differentiation and functions. The aim was to evaluate hrIL-2 efficacy in lymphopenic neonates with severe bacterial infections in NICU.

Materials and methods: Group 1 included 85 septic neonates with lymphopenia treated twice with hrIL-2 100000 IU/kg per day I.V. Group 2 consisted of 60 septic neonates with lymphopenia under standard treatment without hrIL-2.

Clinical cases or summary results: Mortality rates were reduced in group 1 in comparison with group 2 (8% (7/85) vs 20% (12/60), respectively;  $\delta = 0.047$ ). By the 7th day after detection of lymphopenia and inclusion in the study neonates in group 1 had higher total lymphocyte count (3.7 [2.6; 5.5]  $(\times 10^9/L)$  vs 3.1 [1.8; 4.6]  $(\times 10^9/L)$ , respectively, ( $\delta = 0.011$ ) and lymphocyte subpopulation counts than babies in group 2 (CD3+ (63% [61; 70] vs 54% [46; 61], respectively;  $\delta = 0.006$ ); CD8+ (22% [16; 28] vs 15% [10; 18], respectively,  $\delta = 0.002$ ); CD16+CD56+ (0.31 [0.18; 0.81]  $(\times 10^9/L)$  vs 0.16 [0.08; 0.32]  $(\times 10^9/L)$ , respectively; ð < 0.001). Serum IL-8 levels were higher in group 2 compared with group 1 (114 [42; 300] pg/ml vs 34.8 [18.9; 94.8] pg/ml, respectively;  $\delta = 0.002$ ).

**Conclusions:** Treatment with hrIL-2 allows to improve outcomes and reduce mortality rate in neonatal sepsis complicated with lymphopenia.