## The long-term monitoring and analysis of outcomes of different approaches to the management of chronic spontaneous in adolescents

Vera Kalugina<sup>1</sup>, Leyla Namazova-Baranova<sup>1, 2, 3</sup>, Elena Vishneva<sup>1, 2</sup>, Polina Arimova<sup>1</sup>, Lianna Aslamazyan<sup>1</sup>

- <sup>1</sup> Research Institute of Pediatrics and Children's Health in "Central Clinical Hospital of the Russian Academy of Sciences", Moscow, Russian Federation
- <sup>2</sup> Pirogov Russian National Research Medical University, Moscow, Russian Federation
- <sup>3</sup> Belgorod National Research University, Belgorod, Russian Federation

**Background.** Second-generation of H1-antihistamines (H1-AH) is the main therapy for the chronic spontaneous urticaria (CSU). Omalisumab (Omab) is the only biological, approved for the severe H1-AH resistant CSU in adolescents over 12 years.

**Objective.** To evaluate different approaches to severe CSU therapy in adolescents and assess achieving of disease control in 3 y period.

**Methods.** The long-term prospective observation study of 34 children with severe CSU (55% boys, average age 13 yo (min 3; max 17,0), the duration of disease — 33 mo (min 3; max 144); UAS7 — 18 points (min 16; max 24,0) was conducted. All patients received H1-AH for minimum 3 mo.

Patients were randomized in 2 groups. 17 patients of the 1st group were added with Omab to therapy: 55,6% girls, average age — 15 y (min 12,0; max 17,0); disease duration was 45,2 mo (min 3,0; max 144,0), the average total IgE level — 348,2 IU/mL (min 0,8; max 2041,0); the average UAS7 at debut — 17,2 points (min16; max 24). The course of Omab therapy was 6 mo, 300 mg/mo subcutaneously.

17 patients of the 2 nd group maintained alone H1-AH therapy: 64.7% boys, average age — 10.8 y (min 3.0; max 15.0); disease duration was 20.5 (min 3; max 72)

mo, the average total IgE level - 182 IU/mL (min 20; max 1050); UAS7 at debut - 18 (min 16; max 28) points.

The efficacy of therapy assessed by urticaria activity score for the 7 days (UAS7).

**Results.** In the 1st group of patients in 6 mo of Omab therapy UAS7 was 1,6 (min 0; max 20) points, p < 0.05. After 3 y of the course Omab therapy UAS7 was 4,5 points, p < 0.05.

In the 2 nd group of patients, who received alone H1-AH, in 6 mo UAS7 remained at the same level — 18 points (p < 0.05). The average UAS7 in 3 y was 12 (min 0; max 26) points (p < 0.05).

Thus, in patients receiving Omab UAS7 significantly decreased after 6 mo.

The UAS7 level in the Omab group indicates a greater proportion of children who have achieved disease control. The proportion of children, who have achieved remission during 3 y (UAS7 = 0): in Omab group 52,9%, in H1-AH - 29,4% (p = 0.163).

**Conclusion.** Our results indicate the efficacy of Omab in adolescents with CSU: rapid relief of urticaria symptoms and a greater proportion of adolescents who have achieved disease control, compared with therapy alone H1-AH.