International Doctoral School
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Paulina Barasińska
Department of Dermatology, Pediatric Dermatology and Oncology Clinic, Medical University, Lodz/ Department of Pediatric Dermatology

The evaluation of the the efficacy, safety, and tolerability of methotrexate at a dose of 0.3 milligrams per kilogram of body weight per week in children (>2 y.o.) and adolescent subjects with moderate-to-severe atopic dermatitis who are candidates for systemic therapy.

Introduction: Atopic dermatitis (AD) is a chronic and recurrent skin disorder with no curative treatment currently available. Although in majority of cases AD begins in early childhood, no treatment is approved for patients younger than 6 y.o. not responding to topical treatment. There is therefore a clear and compelling unmet need to assess the efficacy and safety of systemic treatment of moderate-to-severe AD in the pediatric age groups.

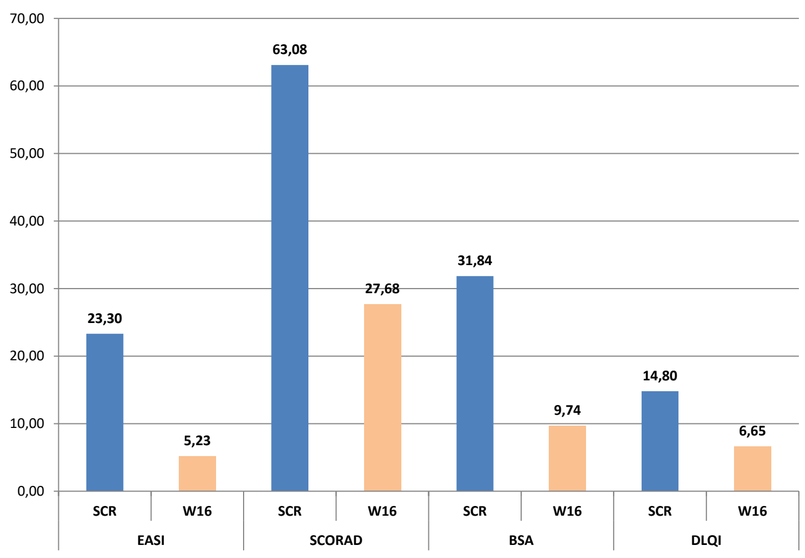
Objective: The study is conducted in Department of Dermatology of the Medical University in Lodz within the project STEADY. The aim of this trial is to assess efficacy, safety and tolerability of methotrexate in children and adolescents (2-18 y.o.) with moderate-to-severe AD.

Methods: Children above 2 years old and adolescents with moderate-to-severe AD measured by EASI>16, BSA>10 and SCORAD>25 who are eligible for systemic therapy were participating in this study. Methotrexate is given in a dose of 0.3mg/kg, once a week. The control point was after 16 weeks of treatment.

- 2-18 yo.
- AD > 6 months
- EASI>16
- SCORAD>25
- BSA>10%

Results: 65 patients (mean age 8 y.o.; 30 girls, 35 boys) have been recruited, of whom 52 have completed the 16th week of observation. 5 patients were excluded from the study. On the basis of the collected data, we have noted an improvement in the clinical condition assessed with the SCORAD scale by an average of 56%. 90,3% of patients achieved EASI50, 69,2% EASI 75 and 36,5% EASI 90. The area of affected skin (BSA) decreased by an average of 69% in randomized population. The most common adverse events reported on follow-up visits were infections of upper respiratory track (39%) and nausea (20%).

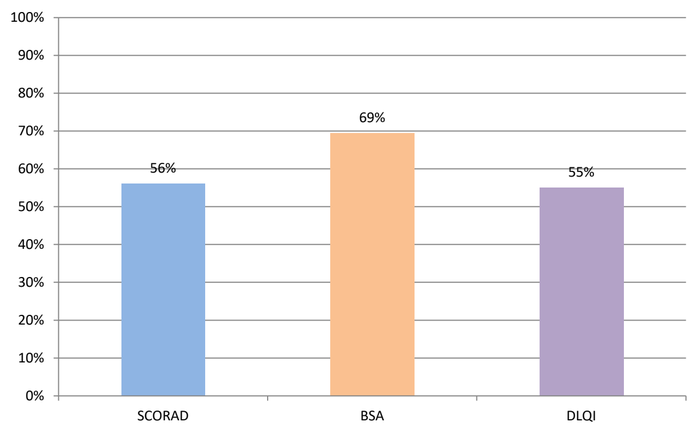
- 65 RECRUITED PATIENTS
- 52 PATIENTS COMPLETED 16TH WEEK OF OBSERVATION
- 5 PATIENTS WERE EXCLUDED



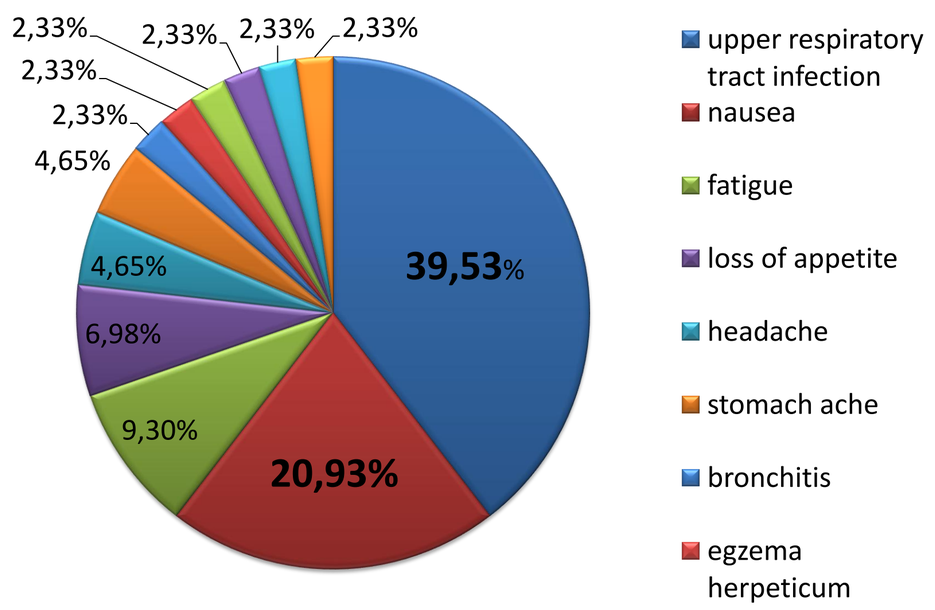
Rys. 1. Comparison of disease severity scales at the screening visits and at week 16 visits.

EASI 50	90,3 %
EASI 75	69,2%
EASI 90	36,5%

Tab.1. Percentage of patients who achieved EASI50, 75, 90.



Rys. 2. Improvement in the clinical condition assessed with the patient's questionnaires during the 16-week follow-up.



Rys. 3. Adverse events related to investigational medicinal product.

Summary: The preliminary results of the present clinical trial show good clinical effectiveness and safety profile of methotrexate and we do hope that in future they will enable to create treatment algorithms for children with moderate-to-severe AD.

Consent of the Bioethics Committee No RNN/155/23/KE 13.06.2023r.