International Doctoral School
Medical University of Lodz

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.

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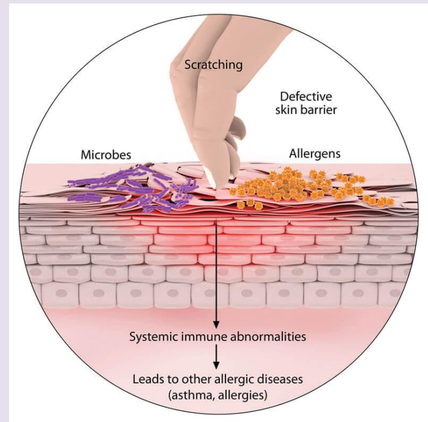
INCLUSION CRITERIA

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

RESEARCH PROJECT

➢ After providing written informed consent, patients are assessed for eligibility at the screening visit. Laboratory tests and medical history must be assessed at this time.
➢ Methotrexate is given in a dose of 0.3mg/kg, once a week, max. dose 20 mg/week, for 16 weeks.
➢ Laboratory tests and clinical evaluation are performed in consecutive weeks (2, 4, 8, 12 and 16) during study visits.
➢ The patients are obliged use emollients twice a day for the whole treatment period, starting on the screening visit.

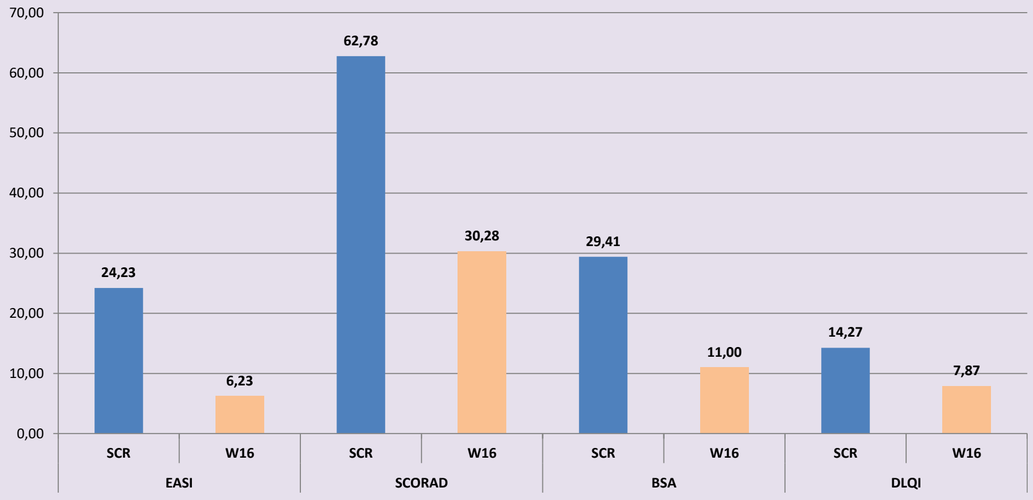


RESULTS

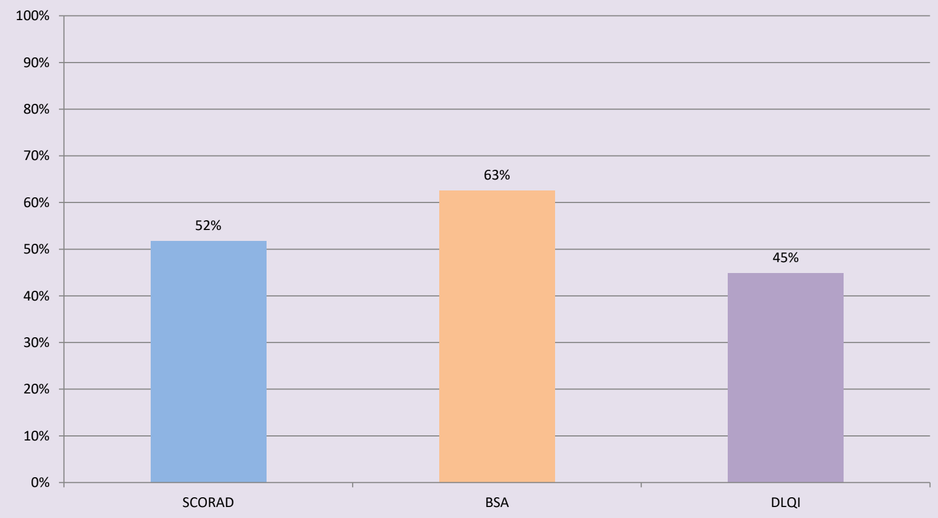
- 43 RECRUITED PATIENTS
- 35 PATIENTS COMPLETED 16TH WEEK OF OBSERVATION
- 4 PATIENTS WERE EXCLUDED

EASI 50	86,7%
EASI 75	66,7%
EASI 90	33,3%

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

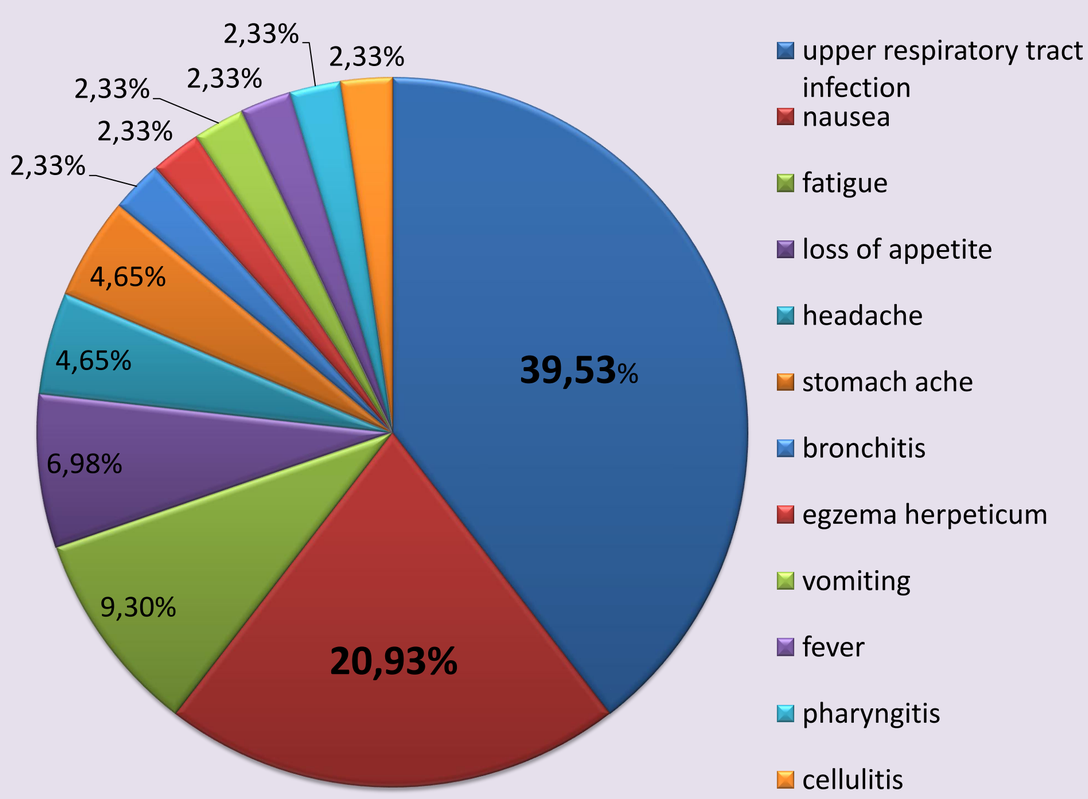


Rys. 1. Comparison of disease severity scales at the screening visits and at week 16 visits.



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

28% OF VISITS WITH REPORTED ADVERSE EVENTS



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