P01-219 - **CLINICAL EFFICACY OF TENOTEN FOR CHILDREN IN TREATMENT OF ATTENTION DEFICIT AND HYPERACTIVITY DISORDER**

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Objectives: To assess efficacy and safety of tenoten for children (TC, ultra-low doses of antibodies to S100 protein) in ADHD patients.

Methods: In a double-blind placebo-controlled study 50 children (6-12 years) met DSM-IV criteria, mild/moderate CGI-ADHD-Severity and ADHDRS-IV-Parent:Inv > 22 points were enrolled. Patients were randomized to receive either TC (2 tablets BID, n=25) or placebo (n=25) for 12 weeks. ADHD symptoms were assessed by ADHDRS-IV-Parent:Inv, CPRS-R:S and CGI-ADHD-Severity.

Results: According to both parents and investigators assessment TC decreased ADHD symptoms: ADHDRS-IV total score reduced by 13.5 points, hyperactivity by 6.7 points, inattention by 6.8 points (5.4, 2.3 and 3.2 in placebo); CPRS-R:S total score reduced by 12.8 points, hyperactivity by 3.6 points, inattention by 6.1 points (4.8, 1.8 and 1.7 in placebo). ADHD severity reduced in 9 patients received TC and 3 patients received placebo. No adverse effects were reported in both groups.

Conclusions: The study demonstrated good clinical efficacy and safety of TC in children with ADHD.

	Total score (M±m)		Hyperactivity (M±m)		Inattention (M±m)	
	Baseline	12 week	Baseline	12 week	Baseline	12 week
ADHDRS-IV						
TC	34.2±1.39	20.7±1.84**	15.8±1.00	9.1±1.06*	18.4±0.63	11.6±0.96**
Placebo	33.6±1.26	28.2±1.82	15.0±0.87	12.7±0.99	18.7±0.51	15.5±0.96
CPRS-R:S						
TC	47.6±2.46	34.8±2.61**	9.7±0.79	6.1±0.58***	23.5±1.07	17.4±1.15***
Placebo	51.9±2.25	47.1±2.59	11.3±0.75	9.8±0.79	24.9±0.93	23.2±0.99

[Table]

,,*** - p< 0.05; p< 0.01; p< 0.001 vs placebo

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