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Results of the Multicenter Study of Cortexin Efficacy in Children with Cognitive Dysfunction

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Importance

According to the results of the study carried out by the Spanish pediatricians in 2017, neuropsychiatric disorders reach 18% among children aged 6–10 years, and ADHD takes the first place in the structure of up to 5.8%, speech disorders account for 3.42%, learning disorders account for 3.26%, anxiety-depressive disorders account for 2.4%, and behavioral disorders account for 1.8%, with comorbid symptoms in half of children. According to the authors, most children with psychoneurological disorders need additional training classes, social adaptation, and one third of patients need medicinal treatment [1]. In addition to training and psychotherapeutic assistance, it is appropriate to search for and administer modern medications without any psychotropic effects and stimulating brain neuroplasticity that would help to cope with attention deficit, speech disorders and asthenic personality disorders. Cortexin (C) has been administered in pediatrics since the beginning of 2000. Most of researches are focused on therapy of motor and cognitive disorders; the authors of such research have concluded that there is a certain drug effect in a complex rehabilitation to acquire psychomotor skills [2, 3, 4]. Cortexin administration has demonstrated positive results in ADHD patients leading to regress of inattention and hyperactivity manifestations [5].

The drug is a complex of neuropeptides of animal origin acting as a stimulator of neuroplastic brain function. The following brain proteins interacting with Cortexin have been found: three neuron-specific proteins tubulin β5, component of the cytoskeleton microtubules, and protein 14-3-3 α/β that belongs to the adaptor proteins affecting other peptides; actin participating in neuronal migration, reparation and differentiation, cytoskeleton protein widely found in many tissues and B-type creatine kinase, enzyme of cell energy metabolism [6]. Cortexin has been shown to increase dopamine levels in the brain in experimental studies, which does not exclude its administration in memory and attention deficits [7].

The purpose of this study was to evaluate the efficacy of cortexin in cognitive dysfunction in children.

Materials and methods: 635 patients aged 3 to 7 years, divided into 4 groups were enrolled. Group 1 included 269 ADHD children, group 2 included 215 children with developmental disorders of speech and language (DDSL), group 3 included 82 patients with perinatal lesions of the central nervous system (PLCNS), and group 4 consisted of 69 children with astheno-neurotic syndrome.

The observation period included 2 visits; the drug was administered intramuscularly, a total of 10 injections. The following statistical methods were used in the study: Wilcoxon test, Pearson's chi-square, Mann-Whitney test; the differences in the compared parameters at <0.05 were taken as significance criteria.

Results and Discussion

The below tables (Table 1 and Table 2) contain data on high efficacy of Cortexin in all cognitive spheres (attention, memory and thinking) suggesting that the drug effects are not age-dependent.

Results of cortexin therapy with assessment of tests at visit 2 within 30 days from the first patient examination in the 3-4-year old subgroup.

		Mean ± standard error of the mean	Median	Minimum	Maximum	p (Wilcoxon test)
						1/2
Attention test	visit 1	4.07 ± 0.21	3.00	0.00	13.00	<0.001
	visit 2	6.13 ± 0.24	6.00	0.00	16.00	
Thinking test	visit 1	3.74 ± 0.15	4.00	0.00	9.00	<0.001
	visit 2	5.59 ± 0.18	6.00	1.00	10.00	
Visual memory test	visit 1	3.77 ± 0.21	4.00	0.00	10.00	<0.001
	visit 2	5.75 ± 0.27	6.00	0.00	14.00	

Table 1. Data on high efficacy of Cortexin in all cognitive sphere

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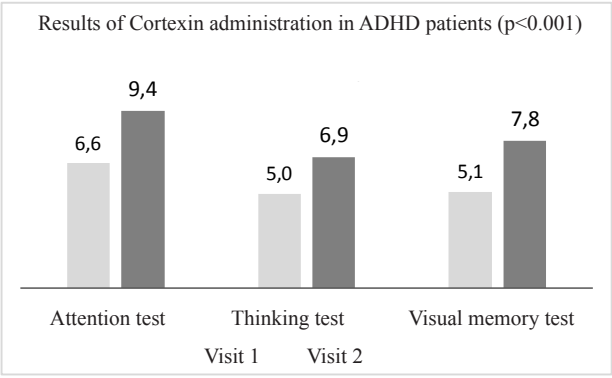
Results of cortexin therapy with assessment of tests at visit 2 within 30 days from the first patient examination in the 5-7-year old subgroup

		Mean ± standard error of the mean	Median	Minimum	Maximum	p (Wilcoxon test)
						1/2
Attention test	visit 1	7.44 ± 0.15	7.00	0.00	17.00	<0.001
	visit 2	10.57 ± 0.16	11.00	1.00	17.00	
Thinking test	visit 1	5.60 ± 0.08	5.00	0.00	10.00	<0.001
	visit 2	7.45 ± 0.08	7.00	1.00	10.00	
Visual memory test	visit 1	5.95 ± 0.14	5.00	0.00	14.00	<0.001
	visit 2	8.61 ± 0.14	8.00	0.00	14.00	

Table 2. Data on high efficacy of Cortexin in all cognitive spheres

It is interesting to note the analysis of results by clinical groups. ADHD group had significant shifts in attention, visual memory tests at visit 2 (see Table 1), which can be explained by the complex drug action, including modulation of dopamine neurotransmission system and stimulation of the developing child's brain plasticity [7]. The similar data were obtained in all clinical groups (Fig. 1), which can be explained by the mechanism of mutual effects of syndromes in the neuronal-functional networks of the brain.



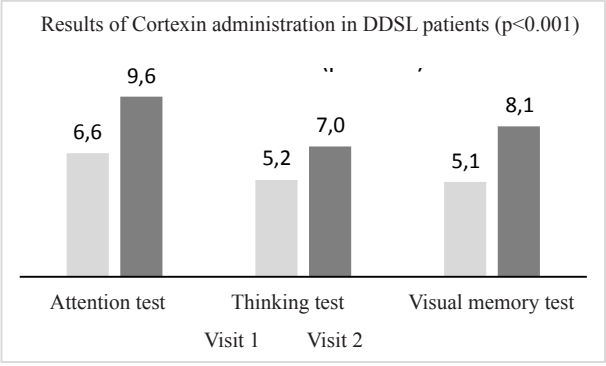


Fig. 1. Results of cortexin administration at visit 2 in groups of patients with ADHD and developmental disorders of speech and language.

The increase of attention function potentiates speech function, visual memory and thinking. In this regard, it is worth noting the following pattern.

Conclusion

Based on the multicenter comparative case-control study in 635 children aged 3 to 7 years, cortexin administration in doses described in its instructions for use is effective in patients with attention deficit hyperactivity disorder, developmental disorders of speech and language, and sequelae of perinatal central nervous system defects. The concept of the multimodal mechanism of action of cortexin, including dopamine neurotransmitter chain and stimulation of neuroplasticity, is clinically confirmed as evidenced by a wide cohort of patients with attention deficit, speech delay and psychomotor deficits.

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