

of occipital areas, increase of coherence in alpha rhythm and decrease of coherence in delta rhythm was found, and for EEG of frontal areas decrease of coherence in a wide range of frequencies (theta, alpha, beta 1 bands). This type of EEG changes was more characteristic for a test dose of noopept than for a course therapy in both groups of patients. During course therapy group 1 was characterized by significant decrease of coherence in delta rhythm between occipital areas and theta rhythm between frontal areas. In group 2, changes of interhemispheric coherence at the end of treatment were statistically nonsignificant.

Thus, noopept caused EEG changes typical for that induced by nootropic drugs which were more pronounced in the right hemisphere. EEG effects of noopept depended on the character of brain pathology and were more typical for those of nootropic drugs in vascular pathology than in posttraumatic disorders.

P.5.038 Clinical pharmacological study of the novel peptide nootropic drug noopept

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Noopept (N-phenylacetyl-L-prolylglycine ethyl ester), a novel original peptide drug with nootropic and neuroprotective activity, was developed at Zakusov Institute of Pharmacology. A standard clinical pharmacological study of noopept (with previous placebo control, using psychological, psychophysiological methods and EEG) was carried out on 40 patients with psychoorganic syndrome. All patients had organic asthenic disorders (emotional lability) of vascular and posttraumatic genesis (F06.60, F06.61). The test dose of noopept was 5 and 10 mg, and during the course treatment – 15 and 30 mg per day. Clinical trials lasted 28 days. It was shown that noopept doses of 15 and 30 mg per day relieved the main symptoms of organic disease: cerebroasthenic, hyperesthetic and sleep disturbances, vegetative dysfunctions as well as cognitive and dismestic problems (attention, memory, efficacy of activity). Therapeutic effects of noopept were connected with mild stimulatory, anxiolytic, nootropic effects and vegetostabilization. The stimulatory effect differed from that of psychostimulators: it was not accompanied by anxiety, aggressiveness, sleep and vegetative disturbances. The medicine did not demonstrate real hypnotic effect, but clear positive normalizing influence on nocturnal sleep was revealed. The specific nootropic effect of noopept developed after a latent period, starting from the 3–4th week of therapy,

which agrees with traditional dynamic characteristic of medicines with nootropic action. A positive effect in cognitive disorders was also observed (improvement of memory, attention, minimization of mistakes with interference, improvement of short memory). The most marked improvement was in attention (distribution, stability and volume), increase of complex sensorimotor reactions, volume of short visual memory. The analysis of EEG showed general improvement in alpha-rhythm frequencies, decrease in delta-rhythm frequencies and increase in beta-rhythm in frontal and central parts of the brain.

It was established that noopept is an effective drug for the treatment of psychoorganic disorders with cerebroasthenic and cognitive disturbances. Equal therapeutic response was observed in patients of young and medium age with the course of 30 mg daily. With the course of 15 mg daily younger patients with psychoorganic syndrome of posttraumatic origin showed better results. The present study of noopept demonstrated that during therapy of asthenic disorders of organic nature the effect of the medicine is characterized by non-specific “fast” antiasthenic and anxiolytic effect, as well as by specific nootropic effect. The results obtained suggest that noopept could be employed in clinical practice as effective nootropic drug.

P.5.039 Experimental and clinical pharmacokinetics of noopept

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The present study was conducted with the purpose to examine experimental and clinical pharmacokinetics of a new dipeptide drug noopept (N-phenylacetyl-L-prolylglycine ethyl ester) possessing nootropic, anxiolytic and neuroprotective activities [1]. The experiments have been performed using high performance liquid chromatography technique. The results obtained from experimental pharmacokinetic studies showed noopept to be more resistant to the action of metabolizing enzyme systems as compared to naturally occurring neuropeptides. Noopept was determined in rat blood plasma independently of the route of administration for 25 min. Noopept was subjected to an intense biotransformation thus demonstrating rather low bioavailability. Pharmacokinetic investigation was carried out with two formulations for peroral usage: tablets (Technological Department of Zakusov State Institute of Pharmacology RAMS) and capsules (DVD Pharma Inc.,