Scientists develop a drug for the treatment of multiple sclerosis

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A team of scientists has created a new form of a vaccine used for the treatment of multiple sclerosis, one of the most severe neurodegenerative autoimmune diseases. The drug has successfully passed pre-clinical trials and two clinical stages. If the results of the third stage are positive, the drug will be approved for the treatment of patients with multiple sclerosis. The results are published in the *Neurotherapeutics* journal.

Multiple sclerosis (MS) is a neurodegenerative disease in which the protective myelin sheath surrounding nerve fibers becomes damaged. This process leads to a gradual loss of nervous system functions that are associated with physical and psycho-emotional states. In Russia, the disease affects more than 200,000 people between the ages of 15 and 25 years, which makes it a complex social problem.

"Many laboratories around the world are working toward effective solutions for the treatment and therapy of multiple sclerosis," says Alexey Belogurov, Ph.D. in Chemistry, one of the authors of the article. "Despite the prevalence of the disease, there is no ideal drug for its treatment, and most existing drugs cause side effects. In Russia, the absolute majority of the drugs are purchased abroad using budget funds. For example, one of the most popular drugs costs over 3 billion rubles annually. It is obvious that, in order to solve social and economic problems, it is necessary to create high-quality domestic medications, and this is what we are now doing."

Scientists from the Institute of Bioorganic Chemistry of the Russian Academy of Sciences proposed a vaccine whose main component are liposomes (lipid vesicle conveyers). They contain fragments of myelin protein, which insulates nerve fibers in the body. In the experiment, three protein fragments were selected, one of which has a therapeutic effect in the early stages of the disease. The other two are used to prevent the development of pathologies during the remission stage. In the laboratory, it was found that the most effective option is the co-administration of all three fragments inside mannosylated liposomes.

Preclinical tests were carried out on dark agouti (DA) rats suffering from experimental autoimmune encephalomyelitis, which is similar to multiple sclerosis in humans. The results established the positive effect of the myelin protein fragments. The researchers then worked toward a vaccine. Previous laboratory achievements were implemented in the development of the drug, and in particular, the myelin protein fragment encapsulation technique using an environment of unilamellar liposome peptides.
"The vaccines developed were tested in a series of clinical trials on healthy volunteers and patients suffering from multiple sclerosis. These trials were conducted at five national centers in Russia. We discovered that the drug is well tolerated, and has a very low probability of developing adverse events," says Alexey.

In the 2006-2008 period, laboratory researchers were able to demonstrate the significance of myelin basic protein and its prospects for use in research and in the treatment of multiple sclerosis. During that time, scientists investigated autoantibodies from blood serum collected from patients suffering from multiple sclerosis and from laboratory animals that were developing experimental autoimmune encephalitis. This series of studies was the starting point in the development of an effective treatment for this disease.

All that remains is to wait for the results of the final phase of the clinical trials, which will allow the new drug to enter into clinical practice for the treatment of multiple sclerosis.

More information: Alexey Belogurov et al. CD206-Targeted Liposomal Myelin Basic Protein Peptides in Patients with Multiple Sclerosis Resistant to First-Line Disease-Modifying Therapies: A First-in-Human, Proof-of-Concept Dose-Escalation Study, *Neurotherapeutics* (2016). DOI: 10.1007/s13311-016-0448-0

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