

CLINICAL TRIALS AND PROGRESS IN MEDICINE

Is it possible that, one day, someone will come up with a cure for Alzheimer's disease or multiple sclerosis? There is no doubt that thanks to the development of medicine, there is a chance for it. Clinical trials are a very important element of this development. Anna Kubiak - coordinator of clinical trials at Dr. Hanka Hertmanowska Memorial Neurological Non-Public Health Care Center and MS Treatment Institution describes how conducting of the trials looks like in practice.

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What is a clinical drug trial and what is its purpose?

Anna Kubiak: A clinical trial for a drug is a carefully planned process in which healthy volunteers or patients are involved. The goal of clinical trials is to discover or confirm the efficacy and safety of tested drug. Research allows progress in medicine - thanks to it, it is possible to introduce new, more effective methods of treatment.

Is the conduct of clinical trials regulated in some way? Are all studies around the world carried out under the same rules?

To ensure the reliability of data obtained as a result of clinical trials and to protect the interests and rights of people participating in them, strict rules have been developed – they are called Good Clinical Practice (GCP). The internal inspection authorities of pharmaceutical companies, bioethics commissions and the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products monitor the adherence of these practices. People involved in the research must be familiar with and adhere to the GCP principles.

What are the next stages of research and what is the goal of these stages? How many participants do they usually include?

Clinical drug trials take place in four phases. Each of them must be successfully completed so that the next stage can be started. During the first phase of the research, the safety of the tested substance is initially assessed. The results allow to pre-determine the dosage of the drug. Several dozen healthy volunteers usually participate in the first phase of the trials. The second phase of the trial is to show whether the drug works in a specific group of patients

and to confirm its safety. During this phase, the relationship between the dose and the effect of the preparation is established. II phase studies include several hundred volunteers - patients suffering from the disease. In the third phase of the trial, conducted with the participation of several thousand patients, the effectiveness and safety of the tested drug in a specific disease entity are finally confirmed. The study is carried out on a larger number of patients in order to obtain the widest possible and at the same time accurate image of the tested product. In addition, the successful completion of phase III allows to start efforts to register a new drug and introduce it into the market. All data obtained during preclinical and clinical trials in phases I to III is a mandatory part of the documentation required by the institutions involved in the registration of medicines. The fourth phase of clinical trials applies to medicines already registered and available for purchase. Its purpose is to confirm safety in all indications recommended by the manufacturer. In addition, this stage of research additionally verifies previously obtained results.

What research do you conduct at your Center?

We are currently conducting research on drugs for multiple sclerosis and Alzheimer's disease in phases II and III. We plan to extend the therapeutic areas of our clinical trials to include internal diseases, dermatology, psychiatry and rheumatology. I encourage you to look at our website- in the NEWS tab, you can find information about our current research.

What is your role in these trials ?

I am the coordinator of clinical trials. My role is above all the cooperate closely with the main trial coordinator (the doctor responsible for conducting the clinical trial) and with the entire research team. Coordinator is more than just a good organizer. He or she deals with the administrative organization of the research at the Center. At one of the trainings I heard a beautiful description of my profession: "The main coordinator is the brain of the clinical trial, and the coordinator is the heart".

What is your job about?

I am involved in the preparation of research documentation, I check its completeness and accuracy. I am a liaison between the research team and the person monitoring the clinical trial. I participate in opening, closing, monitoring visits and audits, as well as in meetings of researchers. I participate in the execution of the entire clinical trial project. From the patient's first visit to the last. I am also responsible for maintaining proper communication with patients, including calendar and visit management in accordance with the protocol. My responsibilities also include correct and timely data entry into the CRF - Case Report Form, in which information obtained from the trial is recorded.

Does this job give you satisfaction?

Of course, especially when I know that I have completely fulfilled my duties and when research supervisors confirm this. Dr. Hanka Hertmanowska – the founder and the main coordinator of our Center was the one who installed in me passion and job involvement. It is thanks to her that I started my adventure in clinical trials. She was my undisputed authority. After her passing, we have been trying to continue her work. As I said at the beginning - clinical trials contribute to the progress of medicine and the thought that I also have a small share in it is very satisfying

**NEUROLOGICAL NON-PUBLIC HEALTH CARE CENTER
MULTIPLE SCLEROSIS TREATMENT INSTITUTION
CLINICAL TRIAL FACILITY
Dr. Hanka Hertmanowska Memorial Clinic**

- clinical trials in the field of neurological diseases
- comprehensive, monitored treatment of multiple sclerosis
- comprehensive, monitored treatment of Alzheimer's disease
- comprehensive neuropsychological consultations
- neurological consultations – diagnostically difficult neurological disorders and symptoms: differential diagnosis, treatment program development, monitoring the course of the disease
- borreliosis and tick-borne infections in neurological diseases - diagnosis and treatment

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