



The Centre for Clinical Trials Regensburg

The University Hospital Regensburg – the most recent university hospital in Germany – established a Centre for Clinical Trials without any public funding.

The ZKS Regensburg cooperates with all departments and institutions of the University Hospital Regensburg. The high number of 200 newly registered clinical trials per year shows the commitment of the University Hospital Regensburg to clinical research. As a service provider and research partner, the ZKS Regensburg supports clinicians in all aspects of clinical trials, from design and registration to implementation, evaluation and publication. The University Hospital views such scientific services as indispensable; thus, the ZKS Regensburg has been financed without public funding since its establishment.

At present, the ZKS Regensburg employs 10 members of staff responsible for methodology, biometry and biostatistics, data management, trial coordination, medical editing and translation, training programmes for clinical research personnel as well as quality management. This service portfolio is complemented by project-related cooperations with enterprises at the 'BioPark Regensburg', the management and coordination centre of the biotechnology cluster BioRegio Regensburg, which support the ZKS in monitoring and the setting up of web-based databases. In 2011, the ZKS Regensburg supported more than 50 clinical trials.

Projects 'Transplantation medicine' and 'Tinnitus Centre'

The ZKS Regensburg provides specialist knowledge on the statistical design and analysis of clinical trials in oncology, on outcome analyses (quality of life) as well as on the trial coordination of projects on transplantation medicine and tinnitus symptoms. Projects on transplantation medicine often involve clinical trials with patients after kidney transplantation. Because kidney transplants are a very scarce commodity, such clinical trials need to be prepared in a highly professional manner in order to avoid screening failures. The ZKS Regensburg has established a successful cooperation with the Department of Internal Medicine II (Nephrology) at the University Hospital Regensburg and usually supports several clinical trials simultaneously.

The ZKS Regensburg also supported the University Hospital Regensburg in its establishment as an international Tinnitus Centre. In this externally funded project, the ZKS Regensburg is responsible for setting up an international database that will be used for the study data of 14 trial centres worldwide. The aim of the project is to identify profiles of patients who respond particularly well to certain forms of therapy in order to aid medical decision-making in clinical practice.

Programmes on clinical research and health services research

In the joint funding programme 'Clinical Trials' of the German Research Foundation and the German Federal Ministry of Education and Research, the ZKS supports a multi-centred randomised placebo-controlled clinical trial that was designed by the Departments of Psychiatry and Otorhinolaryngology of the University Hospital Regensburg. This trial investigates the influence of repetitive transcranial magnetic stimulation on tinnitus



symptoms. The trial involves 150 patients, who are evenly distributed to treatment and control groups, in six centres all over Germany.

The ZKS Regensburg also cooperates with the Department of Trauma Surgery within a programme on health services research funded by the German Federal Ministry of Education and Research. Aim of this trial is the evaluation of the first certified Trauma Network in Eastern Bavaria (German abb.: TNO).

Competence in training programmes

Highly qualified clinical research personnel are a prerequisite for the professional implementation of logistically demanding clinical trials. For this reason, the ZKS Regensburg is highly committed to the development and implementation of training programmes. Such programmes have become of even greater importance because, since the beginning of 2008, ethics committees in Bavaria only allow certified investigators to be in charge of clinical trials. In recent years, the ZKS Regensburg has trained more than 500 principal investigators according to the curriculum developed by the KKS-Network. The ZKS Regensburg also offers a 3-week training course for study assistants in cooperation with the Frankfurt Academy for Clinical Research as well as job-specific English courses for clinical research personnel.

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