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Research methods for clinical trials

A short course in design and management of clinical trials

May 13 – May 18, 2018

Pühajärve Spa and Holiday Resort, Otepää, Estonia

Doctoral School of Clinical Medicine

The course covers concepts in the design, conduct, analysis and reporting of randomised controlled trials. The course includes practical exercises and examples along with short (and sometimes spontaneous) lectures.

This course aims to:

- Present a comprehensive overview of basics of clinical trials methods
- Discuss issues around design and planning
- Address management of clinical trials, including recruitment, data collection and quality
- Raise awareness of ethical and publication matters associated with trials
- Encourage academic clinical trials in Estonia: financing, support systems etc.

By the end of this course participants should:

- Understand why randomised controlled trials are important
- Be convinced that a clear protocol is a must before commencing a trial and be able to draft one
- Be able to design and carry out a basic randomised trial and identify issues in trial planning where searching experienced help might be a wise choice

Who should attend?

The course welcomes PhD students and clinicians with interest in clinical trial methods, preferably with a prospect of the practical application of the skills obtained at the course. No previous knowledge of the subject is required, but a solid understanding of general bio-statistical principles is expected. Free communication in English is a must.

To benefit most and to support the group-work based format of course, the participants are expected to actively attend all sessions and have evenings free for extensive group-work and reading.

Faculty

The co-ordinators for the course are dr Katrin Kaarna (University of Tartu and Tartu University Hospital) and dr Alar Irs (Tartu University Hopsital and Estonian Agency of Medicines). The program is chaired by professor Nick Freemantle who is joined by his colleagues from the Comprehensive Clinical Trials Unit (CCTU) at the University College London. The CCTU collaborates with researchers to design, conduct, analyse and publish clinical trials and other well-designed studies (http://www.ucl.ac.uk/cctu).

Nick Freemantle is the Director of the Comprehensive Clinical Trials Unit at UCL. He is also Professor of Clinical Epidemiology & Biostatistics, Department of Primary Care & Population Health, and has a visiting appointment at University Hospitals Birmingham NHS Foundation Trusts.

He runs a busy programme of research in the evaluation of health care and health technologies which encompasses large scale epidemiological studies through randomised controlled trials to individual simulation models in economic analysis. Nick has vast experience in clinical trials across a range of clinical areas and intervention types (pharmaceuticals, medical devices and non drug treatments). He was the statistician responsible for the design and analysis of the landmark CARE-HF trial, which established the mortality benefits for cardiac resynchronisation therapy and has received more than 3000 citations.

The staff members of the UCL CCTU will present examples of trials conducted by the unit and will encourage course participants to work on their own ideas for clinical trials. There will be an emphasis both on protocol development and its effective implementation - considering practical aspects such as the recruitment and consenting of suitable participants, producing relevant study information and materials and working effectively in a team.

UCL Comprehensive Clinical Trials Unit

Tartu University Hospital

University of Tartu Institute of Clinical Medicine

Republic of Estonia Agency of Medicines