

Clinical Trials (Elective)

Credit Value: 10

Course Organiser: Gillian McHugh

Course Instructor(s): Gillian McHugh

Time: Semester 2 Weeks 1-11
Tuesday 14:00-15:50

Short course description: Design of clinical trials, principles of analysis, and interpretation of findings.

Course prerequisites: None

Aim: To introduce students to the role of clinical trials, and the most frequently used designs, together with the principles that underpin their analysis and interpretation.

Learning objectives: Understand the role of the randomised controlled trial in a range of areas of application. Identify appropriate populations for different types of analysis. Understand the principles of analysis. Contribute to the design of clinical trial protocols. Areas to be covered include:

- Basics of clinical trial design
- Randomisation, avoidance of bias, ethical issues
- Types of trial design
- Parallel groups, cross-over trials, sequential methods
- Sample size
- Explanatory vs pragmatic trials
- Regulatory/organisational aspects
- Analysis of parallel group studies
- Cross-over trials design and analysis aspects,
- Two period trials, multi-period trials N-of-1 trials
- Trials for equivalence
- Use of baseline values
- Interpretation of results multiple testing, subgroup analysis published papers
- Introduction to unusual and advanced methods of design and analysis

Teaching methods: Lectures, tutorials, class exercises

Assessment: Design of a clinical trial protocol