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On-line course materials

MATH38071 - Medical Statistics

Year: 3 - **Semester:** 1 - **Credit Rating:** 10

Requisites

Prerequisites

MATH20701 Probability 2

Aims

This course unit introduces the application of statistical ideas and methodology to medical research.

Brief Description

Randomised controlled trials are planned experimental studies on human subjects designed to assess the benefit of medical treatments. Other important areas of application of statistical methods in medical research are epidemiological studies, which investigate the possible causes of disease from observational data, diagnostic studies, which methods of disease diagnosis and meta-analysis, which considers combining information from multiple studies. Many of the major developments in modern statistics have been motivated by problems in medical research. Whilst briefly outlining other areas of application in medical research, the lecture course will introduce the statistical issue associated design and analysis of randomised controlled trials and in meta-analyses.

Learning Outcomes

On successful completion of this course unit students will

- understand the statistical issues in the design and analysis of clinical trials;
- be able to apply statistical methods to the design and analysis of randomised controlled trials including parallel group, cross-over trials and cluster randomised trials;
- understand the statistical methods used for meta-analysis.

Syllabus

- Introduction to medical statistics. Randomised controlled trials: historical background and ethical issues concerning randomised experimentation on human subjects.

- Design and organisation of randomised controlled trials. Types of bias and methods for controlling bias including blinding and placebo treatments.
- Sample size estimation for continuous and binary outcome measures.
- Methods of treatment allocation including simple randomization, random permuted blocks, stratification and minimization.
- Implications of equivalence and non-inferiority hypotheses for sample size and statistical analyses.
- Statistical methods for the analysis of parallel group trials including methods for the adjustment for baseline data.
- Implications of protocol deviations and the motivation for the intention-to-treat principle.
- Multiplicity issues: sub-group analysis and multiple outcomes.
- Alternatives designs for randomised controlled trials: cross-over trials and cluster randomised trials.
- Meta-analysis and publication bias.

Teaching & Learning Process (Hours Allocated To)

Lectures	Tutorials/ Example Classes	Practical Work/ Laboratory	Private Study	Total
22	11	0	67	100

Assessment and Feedback

- Coursework: weighting 20%
- End of semester examination: two hours weighting 80%

Further Reading

- Matthews, JNS, An Introduction to Randomized Controlled Clinical Trials, 2nd edition 2006, Chapman & Hall/CRCPress

The first edition (2000) is also adequate for this course and there are copies of both in the John Rylands Library

Data source is EPS system

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