ST4241: Design and Analysis of Clinical Trials  
(2015-2016 Semester I)

Schedule:  
Time: Tuesdays & Fridays 8:00-10:00am  
Venue: LT53

Course Objective:  
• To introduce the students to the general knowledge of clinical trials.  
• To equip the students with the methodology for design and analysis of clinical trials.  
• To enable the students to do consultation and data analysis in clinical trials.  
• To nurture general statistical thinking of the students.

Text Book:  
Joseph L. Fleiss  
The Design and Analysis of Clinical Experiments.  
Wiley Classics Library Edition 1999  
John Wiley & Sons.

Assessment:  
Assignments 20%, Middle term exam 30%, Final exam 50%

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Course Outline

Part 0: Introduction

• **Overview of Clinical Trials**
  – What are clinical trials
  – General procedure and principles of clinical trials
  – Statistical designs at a glance

Part I: Clinical trials without control on prognostic variables

• **Parallel groups design**
  – Randomization in parallel groups designs
  – Analysis of variance and multiple comparisons
  – Equality of variance, normality and transformations
  – Non-normally distributed response variable

• **Special cases of parallel groups study**
  – Several treatments versus a control
  – The $2 \times 2$ factorial experiment
  – Bonferroni criterion for multiple comparisons
  – A quantitative experimental factor
Part II: Clinical trials with control on prognostic variables

• Blocking to control for prognostic variables
  – Randomized blocks experiment
  – Analysis of variance for randomized blocks
  – Nonparametric analysis
  – Missing values

• Stratification to control for prognostic variables
  – Comparison of two treatments
  – Treatment by stratum interaction
  – Pre- versus post-stratification
  – Comparison of more then two treatments
  – Multicenter studies

• Latin and Greco-Latin squares design to control particular factors
  – Single $g \times g$ Latin square
  – Replicated Latin squares
  – Variations of the Latin squares

• Crossover study to control subject unit effects
  – Two period crossover study
  – Non-normally distributed response variable
  – More than two treatments
• Balanced incomplete block design
  – Application to an interexaminer reliability study
  – A BIBD as a two-period crossover study

• Repeated measurement studies.
  – Analysis of variance of repeated measurements
  – Multivariate analysis of repeated measurements
  – Multiple comparison involving time
  – A brief introduction to longitudinal data analysis

**Part III: Other topics**

• Factorial Designs.
• Split-plot designs
• Sample-size determination