

數學系課程核心教材內容

課程名稱：(中文) 臨床試驗上的統計方法 (英文) Statistical Methods in Clinical Trials				開課單位	統科碩士班
				課程代碼	2315777
學分數	3	必/選修	選修	開課年級	一
<p>教學目標與課程概述：This is a survey course that stresses the concepts of statistical design and analysis in biomedical research, with special emphasis on clinical trials. This text will be devoted mostly to statistical principles and methods in Clinical Trials research but we will first give a very brief introduction to Epidemiology in the beginning. SAS for Windows statistical software will be used throughout the course for data analysis.</p> <p>先修科目或先備能力：</p>					
建議參考書目	Piantadosi S. (1997). <i>Clinical Trials: A Methodologic Perspective</i> . New York, NY: John Wiley & Sons.				

課程大綱

單元主題	內容綱要	上課週數
Epidemiology	Brief introduction to epidemiology: Type of studies (cross-sectional, longitudinal, cohort study, case-control study), risk difference, relative risk and odds ratio	1-1.5
Concepts of Clinical Trials	Definitions of clinical trials, The use of clinical trials, Clinical Trials as experiment designs, Trial designs types (Phase I, Phase II, Phase III); Bias and random error, Objective and endpoints	2
Sample size and Power	Sample size and power for different type of studies (Dose-finding studies, safety and efficacy studies, comparative treatment efficacy studies, Expanded safety studies), Adjustment factors for sample size calculations	2
Treatment Allocation and Randomization	Principle of randomizations, Constrained randomization, Adaptive randomizations, Administration of the randomization process, Unequal treatment allocation	1-1.5
Estimating Clinical Events	The odds ration, Trend analysis, Survival analysis, Analysis of covariance, Bootstrap analysis	2
Prognostic Factors and Regression Models	ANOVA model, ANCOVA model, Logistic regression model, proportional hazards regression model	2
Crossover designs	Design issues, Type of crossover designs, Analysis of crossover designs, Bioequivalent trials	2
Correlation and Measures of Agreement	Pearson, Spearman, and correlation coefficient, Concordance correlation coefficient, Spearman correlation coefficient, Cohen's Kappa statistics; Diagnostic Testing, ROC curve	2