

Medical Statistics

Exercises 1

(Released 24 October 2011, work submitted by ~Tuesday 8 November 2011 will be marked and returned. Work submitted after solutions are made available will not be marked)

- 1) In the comparison of a new drug A with a standard drug B it is required that patients are assigned to drugs A and B in the proportions 3:1 respectively. Illustrate how this may be achieved for a group of 32 patients, and provide an appropriate randomization list. Comment on the rationale for selecting a greater proportion of patients for drug A.
- 2) The table below gives the age (≤ 55 / >55), gender (M/F), disease stage (I/II/III) of subjects entering a randomized controlled clinical trial at various intervals and who are to be allocated to treatment or placebo in approximately equal proportions immediately on entry.

order of entry	Age	Gender	Stage
1	≤ 55	F	III
2	≤ 55	M	III
3	≤ 55	M	I
4	≤ 55	F	I
5	> 55	F	II
6	≤ 55	F	III
7	> 55	F	I
8	> 55	M	III
9	≤ 55	M	III
10	> 55	F	III
11	≤ 55	F	III
12	≤ 55	M	I
13	> 55	F	I



- i) Construct a randomization list for this group of subjects by a minimization method designed to achieve an overall balance between the factors.
 - ii) Cross-tabulate the treatment received with each [separate] factor.
 - iii) Construct a list to allocate the subjects to treatment completely randomly without taking any account of any prognostic factor and compare the balance between treatment groups achieved on each of the factors.
- 3) In a clinical trial of the use of a drug in twin pregnancies an obstetrician wishes to show a significant prolongation of pregnancy by use of the drug when compared to placebo. She assesses that the standard deviation of pregnancy length is 1.5 weeks, and considers a clinically significant increase in pregnancy length of 1 week to be appropriate.
- i) How many pregnancies should be observed to detect such a difference in a test with a 5% significance level and with 80% power?
 - ii) It is thought that between 40 and 60 pregnancies will be observed to term during the course of the study. What range of increases in length of pregnancy will the study have a reasonable chance (i.e. between 70% and 90%) of detecting?

