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SARDAR PATEL UNIVERSITY
M.Sc. (IV Semester) Examination
2012
Friday, 7th December
2:30 p.m. to 5:30 p.m.
STATISTICS COURSE No. PS04ESTA04
(Clinical Trials)

Note: Figures to the right indicate full marks of the questions. **(Total Marks: 70)**

1 Write correct answers **08**

(a) When population variance gets higher from 1 to 2 the sample size would
(i) doubled
(ii) quadrupled
(iii) remain same
(iv) get smaller

(b) In paired sample test the sample size is smaller than the corresponding independent sample test because
(i) difference to be detected is smaller
(ii) units are measured twice
(iii) within unit variation is smaller
(iv) paired sample variance is smaller

(c) An allocation probability rule in simple randomization with equal group size is
(i) {1/3, 2/3}
(ii) {1/2 , 1/3}
(iii) {0, 1}
(iv) {1/2, 1/2}

(d) The clinical trial study of knowing the effect of Vitamin A vs. placebo in children is a _____ study

(i) Phase I
(ii) Phase II
(iii) Phase III
iv) Phase IV

(e) O Brien test is preferred to Pocock test when
(i) participants are more or less uniform (ii) participant are large in number
(iii) trial must be terminated early (iv) none of these

(f) In meta analysis the statistic used commonly to summarize studies is
(i) Relative Risk (ii) Odds Ratio
(iii) median (iv) Mean

(g) There are ___ strata in a study involving three prognostic factors each with two levels
(i) 3 (ii) 4 (iii) 5 (iv) 6

(h) The **b** % increase in survival is concluded if the Cox regression model coefficient **b** is
(i) negative
(ii) positive
(iii) zero
(iv) one

2 **Answer any 7, each carry 2 marks.** **14**

(a) Define the purpose of Phases I and II of clinical trial study.

(b) Describe the minimization method.

(c) Explain Dose Fining (DF) trial and its application.

(d) Explain how studies involving 'death' as primary response variables are handled alternatively.

(e) Distinguish between phase III and phase IV trials.

(f) Distinguish between random error and bias and Type I error and Type II error.

(g) Name the method and write its assumptions used in estimating survival curve.

(h) Define the confidence interval of hazard ratio.

(i) What is multi center trial?

(j) Explain the concept of group sequential methods.

3 (a) Explain how sample size is reduced in a clinical trial SE and CTE studies. **6**

(b) Discuss sample size derivation in case of comparing two group means. **6**

OR

(b) A study is designed to test continuous responses in pair for subjects receiving treatments A and B. The estimate of $(\mu_A - \mu_B)$ from n pairs of subjects has variance 100. Calculate a sample size required for testing H_o: $\mu_A = \mu_B$ against alternative H_1: $\mu_A \neq \mu_B$ with type I error probability $\alpha = 0.05$ and power $1-\beta = 0.9$ at $\mu_A - \mu_B = \delta = 3.0$

4 (a) Suppose there are 24 patients. Perform blocked randomization to produce two equal size groups. **6**

(b) List all the study designs and give details of any three study designs. 6

OR

(b) Give study design for comparing a treatment and placebo effect which is free from ethical issue of group allocation discrimination. How many patients are needed if each sequence is to be replicated thrice?

5 (a) Define hazard rate and Cox proportional hazard model. Explain how this model is useful in survival analysis. 6

(b) What are prognostic factors? Discuss how presence of prognostic factors is handled in Clinical trials. 6

OR

(b) In a study, 18 participants are followed for a period of 1 year, and to the nearest of tenth of a month, deaths and losses were observed at the following times.

Control Group: deaths at 0.5, 1.5, 1.5, 3.0, 4.8, 6.2 and 10.5 months. In addition losses to follow-up were recorded at: 2.0, 4.0, 8.5 and 9.0 months.

Intervention Group: deaths at 1.0, and 4.5 months. In addition losses to follow up occurred at 1.6, 4.2, 7.0 and 11.0 months.

The remaining 7 participants (C), 12 participants (I) were all censored at 12 months because of termination of the study.

Carry out comparison of two survival curves suitably.

6 (a) Give the steps of meta analysis. Carry out the necessary estimation for the gathered data as given. 6

Sr no	Trial	Treatment	Control
1	CF1	58/605	76/620
2	CF2	126/846	185/878
3	PA1	244/1620	77/406
4	PA2	154/1563	218/1555

(b) Explain the performance of Pocock's test and OBrien Fleming tests along with test which generalizes them both. 6

OR

(b) In a problem of testing the null hypothesis of no treatment mean difference against the two sided alternative: treatment difference of ±1, the type I error was 5% and power was fixed at 90%.
Population variance was 4. If test of significance is to be repeated for 5 times as per Pocock's test, how many more participants would be required than a fixed sample size?

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