Sample size and Power calculations
Exercises

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Exercise 1

A study is being planned to examine the effectiveness of aciclovir suspension (15mg/kg) for treating 1-7 year old children with herpetic gingivostamatitis lasting less than 72 h. It will be a randomized double-blind placebo-controlled trial with "treatment" administered five times a day for 7 days. The main outcome measure for determining sample size is duration of oral lesions.

Exercise 1

a) How many children are required to have a 90% power of detecting a 2.5 day difference in duration of oral lesions between the two groups at the 5% level of significance? The investigators assume that the standard deviation of oral lesions is approximately 5 days.

b) If the difference we want to detect increases to 3 days, what is then the required sample size?

c) If the standard deviation increases to 6 days, what is then the required sample size? (keep a 3 day difference)

Exercise 2

We aim at comparing the incidence of pelvic pain in two groups of women: a treatment group that has undergone a program of preventive exercises with a physiotherapist, and a control group. The probabilities of pelvic pain in these two groups are p_2 and p_1, respectively. The incidence of pelvic pain in the control group is 15%. It is considered important to discover if the incidence is reduced to 8% in the preventive treatment group. Power is set to 80% and the significance level to 5%. How many women do we need in each trial group?

Exercise 3

One group is treated with cholesterol-lowering drug and one group receives placebo. Cholesterol has a standard deviation of 1 mmol/l. The clinically relevant difference between the groups that we want to detect is 0.5 mmol/l. Power is set to 80% and the significance level to 5%. How many individuals do we need in each group?

Exercise 4

We want to estimate the incidence of a particular characteristic among women in a given age group and plan to examine a representative sample of women.

a) The uncertainty in the estimate should not exceed $\pm 10\%$. Expected occurrence is estimated to be 50%. How many women must be in the sample?

b) The uncertainty in the estimate should now not exceed $\pm 3\%$. Expected occurrence is still 50%. How many women must there be in the sample?

c) The uncertainty in the estimate remains $\pm 3\%$, but the expected occurrence is now 20%. How many women must there be in the sample?

Exercise 5

A randomized placebo-controlled trial was carried out to investigate the capacity of aspirin to prevent pregnancy-induced hypertension and preeclamptic toxaemia. The study was carried out on women at high risk of these conditions.

a) How many patients would have been needed to have a 80% power of detecting as significant ($p < 0.05$) a reduction of one-third in the risk of hypertension from 30% to 20%?

Exercise 5

b) The actual sample size was 65. What was the power of the study to detect the difference considered in a)?

c) The observed rates of hypertension were 11/31 (36%) in the placebo group and 4/34 (12%) in the aspirin group. The authors also quoted a relative risk (RR) of hypertension of 0.33 for aspirin vs placebo. Calculate a 95% confidence interval of the RR, and comment on the authors' conclusion that large scale clinical trials are needed.