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Editorial announcement

Summaries of papers reporting results of clinical trials

Most therapeutic trials now follow a fairly standard design and can therefore be summarised in a systematic manner. In order that essential information concerning a trial is easily available to the reader, summaries of papers reporting results of such studies should conform broadly to the scheme set out below. All the topics listed should be included in the text of the summary.

AIM

The aim of the study should be clearly stated – namely, to compare the effect of treatment A *v.* treatment B on the attribute X of disease C. If there are additional hypotheses they should be listed.

DESIGN

The design of the study should be specified and include attributes such as single/multicentre, randomised, crossover, prospective, double/single blind whatever is appropriate. Doses of drugs or other therapeutic agents, routes and frequency of administration can be stated here, or in the next section. Period of treatment must be clearly stated.

SUBJECTS

Statement should include sex ratios, median age if important, numbers entered, numbers finally analysed and the number of dropouts.

ANALYSIS

This should include statements concerning the end point of the variable used to assess the failure, or success of the treatment, methods used for testing for levels of significance and the calculated power of the trial to discriminate at various probability values between stated levels of differences between the treatment groups.

RESULTS

Include a short statement of main results, quoting all p values (not only the significant ones) and/or 95% confidence limits. If important unwanted effects of treatment occurred, they should be mentioned. Extrapolations from data should be placed in the discussion and 'In summary' statements are unnecessary.

NB This is not an invitation to write lengthy summaries. An example is shown below.

In a single centre trial we compared the value of oldidine with newidine in

promoting peptic ulcer healing by comparing the proportions of healed ulcers after two and four weeks of treatment. Two hundred patients (120 men) were randomly allocated according to a prearranged treatment schedule to either drug and were treated double-blind. Each received 250 mg oldidine at night and a matching newidine placebo, or 25 mg newidine at night and an oldidine placebo. One hundred and eighty four patients (86 oldidine and 98 newidine) completed the trial. Sixty two oldidine (72%) and 74 newidine treated (76%) had healed ulcers at two weeks, and 74 oldidine and 83 newidine (86% and 85%, respectively), had healed ulcers at four weeks. The difference was not significant using Fisher's exact test (two tailed) the study having a power to detect a 25% difference on 50% of occasions. Unwanted adverse events were mainly trivial but two newidine treated patients developed severe headache which resolved on stopping treatment.

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Editor