

Paracetamol and Fever

- a **Entry was limited to children with temperatures between 38°C and 41°C.**

Given the mean of 38.9 °C and the SD of 0.9, what can you say about the shape of the frequency distribution over the 38°-41° interval?

- b **"We estimated a sample size requirement of 210 subjects completing the trial" (Sample size — paragraph 5 of Methods)**

Give the formula by which the authors estimated this (identify what numbers go with what parameters, but leave the details to your assistant [who has not taken a statistics course])

- c **"Student's t- test and Mann-Whitney (alias Wilcoxon) test..." (Statistical testing — paragraph 5 of Methods)**

Why did the authors use the Mann-Whitney (alias Wilcoxon) test? In light of the n's and the shape of the distribution of duration of fever, was their concern about the use of the t test justified?

Q4 Paracetamol and Fever (continued)

d "The mean duration of fever..." [paragraph 4 of Results]

Explain in a sentence, in non-technical words, the phrase "the differences were statistically non-significant"

e "The 95% CI for the differences between the paracetamol and placebo groups for duration of fever was -10.0 to +7.1 h"

Explain in non-technical words what this statement says.

f How does this CI add to what is shown in Figure 1?

g How was the CI calculated

Q4 Paracetamol and Fever (continued)

- h** Before the study, the authors anticipated a SD of 2 days (48 hours) for the duration of fever. The SD of the duration of fever observed in the n=225 is not reported explicitly.

How could one reconstruct this SD from the results given [assume that the SD is the same in the two treatment groups]?

- i** "Children..were more likely to be rated.as having at least a 1-category improvement in activity...." [2nd last paragraph of Results]

What tests could be used to compare the two groups? Do they all give the same answer?

- j** "*On the basis of ...completing the trial*" [sample size considerations, first sentence of paragraph 5 of Methods]

"There were no significant differences between groups in mean duration of subsequent fever" [Abstract]

If these two statements were the ONLY information you were given about the trial, what could you conclude?

Q5 Melatonin and Delayed Sleep

- a What sample size formula or table would you have shown the authors if they had consulted you concerning sample sizes before doing their study?
- b What is it about the study design that makes the required sample size so much smaller than that in Kramer's study?
- c What do you consider would be a clinically significant advance in sleep onset time?

d "In all 8 subjects sleep onset time was earlier during melatonin treatment than during placebo" [Abstract]

List 3 possible tests of these data, putting them in order of increasing statistical power [do not carry out the tests, but give references]

- e Set up the calculation from which the $p < 0.01$ for the 3.49 versus 2.12 [Table II, sleep onset time, melatonin versus placebo] was derived
- f Are there sufficient data in the table to allow you to verify the calculation?