





Critical appraisal - Internal validity

The topic is...

Internal validity refers to the extent to which the observed effect in a study can be attributed to the treatment rather than to other factors. It is the degree to which the study design and conduct minimize the risk of bias and confounding.

Internal validity is a key component of the overall validity of a study. It is essential for the study to be able to answer the research question accurately.

Internal validity is affected by several factors, including:

- Selection bias
- Information bias
- Confounding
- Measurement error
- Loss to follow-up
- Non-compliance
- Dropouts

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Study overview - Methods

Intervention

Patients were randomised into two study arms to receive saline placebo or ondansetron 2 mg loading dose over 20 min, then a constant infusion of 0.5 mg/h until a maximum of 7 d, atropine had not been required for 12-24 h, or death).





Study overview - Methods

Intervention
Patients were randomised into two study arms to receive saline placebo or pralidoxime chloride (2 g loading dose over 20 min, then a constant infusion of 0.5 g/h until a maximum of 7 d, atropine had not been required for 12-24 h, or death).







Critical appraisal - Internal validity

• This paper - yes

Randomization
Patients were stratified into one of two study arms to receive either placebo or prophylactic celecoxib (2 g loading dose over 24 h, then a constant infusion of 0.5 g/h until a maximum of 7.4 mg/kg had not been required for 12–24 h, post-randomization). The randomization sequence was generated by computer using a random number generator. Stratified block randomization was used, with a computer-generated random number generator. Stratification factors were clinical site, sex, and age. Allocation in a 1:1 ratio. (ii) concealment: unknown; (iii) status on randomization: not reported; (iv) blinding: not reported; (v) allocation in a 1:1 ratio.

Blinding
The allocation sequence was generated independently by the sponsor and the investigator. The investigator was not involved in the generation of the randomization sequence. The randomization sequence was generated by computer using a random number generator. Stratification factors were clinical site, sex, and age. Allocation in a 1:1 ratio. (ii) concealment: unknown; (iii) status on randomization: not reported; (iv) blinding: not reported; (v) allocation in a 1:1 ratio.



Critical appraisal - Internal validity

- The paper yes

Introduction
Patients were randomised into one of two study arms to receive either placebo (n = 100) or active (n = 100) treatment. The primary outcome was the proportion of patients who were alive at 24 hours. The secondary outcome was the proportion of patients who were alive at 30 days.

Methods
Patients were randomised into one of two study arms to receive either placebo (n = 100) or active (n = 100) treatment. The primary outcome was the proportion of patients who were alive at 24 hours. The secondary outcome was the proportion of patients who were alive at 30 days.

Results
The proportion of patients who were alive at 24 hours was significantly higher in the active treatment group (n = 60, 60%) compared to the placebo group (n = 40, 40%). The proportion of patients who were alive at 30 days was also significantly higher in the active treatment group (n = 50, 50%) compared to the placebo group (n = 30, 30%).

Conclusion
The active treatment significantly improved survival at 24 hours and 30 days compared to placebo.









