

Refid: 12, Skateboards: Are they really perilous? A retrospective study from a district hospital.

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Comparative Effectiveness of Pharmacologic Therapies for the Management of Crohn's Disease
Quality form for RCTs

Sequence Generation

1. Was the allocation sequence adequately generated?

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Criteria for a judgment of "YES" (i.e., low risk of bias)

- The investigators describe a random component in the sequence generation process such as:
 - Referring to a random number table; Using a computer random number generator; Coin tossing; Shuffling cards or envelopes; Throwing dice; Drawing of lots; Minimization. Minimization may be implemented without a random element, and this is considered to be equivalent to being random.

Criteria for a judgment of "NO" (i.e., high risk of bias)

- The investigators describe a non-random component in the sequence generation process. Usually, the description would involve some systematic, non-random approach, for example:
 - Sequence generated by odd or even date of birth;
 - Sequence generated by some rule based on date (or day) of admission;
 - Sequence generated by some rule based on hospital or clinic record number.
- Other non-random approaches happen much less frequently than the systematic approaches mentioned above and tend to be obvious. They usually involve judgment or some method of non-random categorization of participants, for example:
 - Allocation by judgment of the clinician;
 - Allocation by preference of the participant;
 - Allocation based on the results of a laboratory test or a series of tests.

Criteria for a judgment of "UNCLEAR" (i.e., uncertain risk of bias)

- Insufficient information about the sequence generation process to permit judgement of "YES" or "NO."

Allocation Concealment

2. Was allocation adequately concealed?

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Criteria for a judgment of "YES" (i.e. low risk of bias)

- Participants and investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation:
 - Central allocation (including telephone, web-based, and pharmacy-controlled, randomization);
 - Sequentially numbered drug containers of identical appearance;
 - Sequentially numbered, opaque, sealed envelopes.

Criteria for a judgment of "NO" (i.e. high risk of bias)

- Participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, such as allocation based on:
 - Using an open random allocation schedule (e.g. a list of random numbers);
 - Assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or non-opaque or not sequentially numbered);
 - Alternation or rotation;
 - Date of birth;
 - Case record number;
 - Any other explicitly unconcealed procedure

Criteria for the judgment of "UNCLEAR" (i.e. uncertain risk of bias)

- Insufficient information about the sequence generation process to permit judgment of "YES" or "NO".

- This is usually the case if the method of concealment is not described or not described in sufficient detail to allow a definite judgment – for example if the use of assignment envelopes is described, but it remains unclear whether envelopes were sequentially numbered, opaque and sealed.

Blinding of Participants, Personnel, and Outcome Assessors

3. Was knowledge of the allocated interventions adequately prevented during the study?

Select an Answer

Criteria for a judgment of "YES" (i.e. low risk of bias)

- Any one of the following:
 - No blinding, but the review authors judge that the outcome and the outcome
 - Blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken;
 - Either participants or some key study personnel were not blinded, but outcome assessment was blinded and the nonblinding of others unlikely to introduce bias.

Criteria for a judgment of "NO" (i.e. high risk of bias)

- Any one of the following:
 - No blinding or incomplete blinding, and the outcome or outcome measurement is likely to be influenced by lack of blinding;
 - Blinding of key study participants and personnel attempted, but likely that the blinding could have been broken;
 - Either participants or some key study personnel were not blinded, and the non-blinding of others likely to introduce bias.

Criteria for the judgment of "UNCLEAR" (i.e. uncertain risk of bias)

- Any one of the following:
 - Insufficient information to permit judgment of 'Yes' or 'No';
 - The study did not address this outcome.

Incomplete Outcome Data

4. Were incomplete outcome data adequately addressed?

Select an Answer

Criteria for a judgment of "YES" (i.e. low risk of bias)

- Any one of the following:
 - No missing outcome data;
 - Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias);
 - Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups;
 - For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate;
 - For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes not enough to have a clinically relevant impact on observed effect size;
 - Missing data have been imputed using appropriate methods.

Criteria for a judgment of "NO" (i.e. high risk of bias)

- Any one of the following:
 - Reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups;
 - For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate;
 - For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes enough to induce clinically relevant bias in observed effect size;
 - 'As-treated' analysis done with substantial departure of the intervention received from that assigned at randomization;
 - Potentially inappropriate application of simple imputation

Criteria for the judgment of "UNCLEAR" (i.e. uncertain risk of bias)

- Any one of the following:
 - Insufficient reporting of attrition/exclusions to permit judgment of 'Yes' or 'No' (e.g. number randomized not stated, no reasons for missing data provided);
 - The study did not address this outcome.

Other Potential Threats to Validity

5. Was the study apparently free of other problems that could put it at a risk of bias?

Select an Answer

Criteria for a judgment of "YES" (i.e. low risk of bias)

- The study appears to be free of other sources of bias.

Criteria for a judgment of "NO" (i.e. high risk of bias)

- There is at least one important risk of bias. For example, the study:
 - Had a potential source of bias related to the specific study design used; or
 - Stopped early due to some data-dependent process (including a formal-stopping rule); or
 - Had extreme baseline imbalance; or
 - Has been claimed to have been fraudulent; or
 - Had some other problem.

Criteria for the judgment of "UNCLEAR" (i.e. uncertain risk of bias)

- There may be a risk of bias, but there is either:
 - Insufficient information to assess whether an important risk of bias exists; or
 - Insufficient rationale or evidence that an identified problem will introduce bias.

Pharmaceutical Support

6. Did this study receive support (research funds, medications provided, writing services, author or staff was employee) from a company having a financial interest in any of the medications studied?

7. If "Yes," did the company have any involvement in the design, conduct, or reporting of the study?

For "NO," the authors are not employees of the company and the authors had complete access to the data, and the company was not involved in the design, conduct, analysis, or reporting of the study.

Overall Quality of Study

8. Please rate the overall quality of the study:

Criteria for a judgment of "GOOD" (i.e. low risk of bias)

- These studies have the least bias and results are considered valid
- A study that adheres mostly to the commonly held concepts of high quality including the following:
 - A formal randomized controlled study;
 - Clear description of the population, setting, interventions, and comparison groups;
 - Appropriate measurements of outcomes;
 - Appropriate statistical and analytic methods and reporting;
 - No reporting errors;
 - Low dropout rate; and
 - Clear reporting of dropouts

Criteria for a judgment of "FAIR"

- These studies are susceptible to some bias, but it is not sufficient to invalidate the results.
- Do not meet all the criteria required for a rating of good qualities because they have some deficiencies, but no flaw is likely to cause major bias.
- The study may be missing information, making it difficult to assess limitations and potential problems

Criteria for a judgment of "POOR" (i.e. high risk of bias)

- These studies have significant flaws that imply biases of various types that may invalidate the results.
- Have serious errors in design, analysis, or reporting; large amounts of missing information; or discrepancies in reporting.

9. Were >20% of the study participants lost to followup at any of the following time points?

10. Please add comments below.

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