
**Randomized (controlled) trial.** A human trial that involves at least one experimental treatment group and one control treatment group, concurrent enrollment, and follow-up of the test and control groups, and in which the assignment to experimental and control groups is by a randomization process. Neither the subjects nor the persons responsible for treatment can influence the assignments, and the assignments remain unknown to the subjects and staff until eligibility has been determined.

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<tr>
<th>Heading</th>
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<tr>
<td>Title:</td>
<td>1. Content of paper clarified within 135 character limit.</td>
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<tr>
<td>Abstract:</td>
<td>2. Structured per Instructions For Authors. Design identified as randomized controlled trial.</td>
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<td>Introduction:</td>
<td>3. States hypothesis, clinical objectives, and planned subgroup or covariate analyses.</td>
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<td>4. Brief review of pertinent literature.</td>
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<td>Methods:</td>
<td>5. Describe therapeutic intervention.</td>
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<td>6. Describe the study population and clarify whether one or both eyes of patients were included.</td>
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<td>7. Define inclusion/exclusion criteria.</td>
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<td>8. Describe primary and secondary outcome measure(s) and the minimum important (statistically significant) difference(s).</td>
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<td>9. Indicate how the target sample size was calculated.</td>
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<td>10. IRB approval and informed consent requirements completed.</td>
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<td>11. Clarify the method of collecting patients (e.g., consecutive cases from clinic population, etc.).</td>
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12. Detail the main comparative analyses and whether data were analyzed according to the group to which they were originally assigned (e.g., by intention to treat or by treatment as administered).


(Randomization/Masking Issues)

14. Describe assignment by unit of randomization (e.g., eye, individual, cluster, geographic area).

15. Describe the method used to generate the assignment schedule.

16. Describe the method of assignment concealment and timing of assignment.

17. Describe mechanism (e.g., drops, parenteral, tablets), and similarity/dissimilarity of experimental and control treatment characteristics (e.g., appearance, discomfort).

18. Describe the allocation schedule and methods for security (location of code during trial and when broken).

Results:

19. Describe evidence for successful masking (blinding) among participants, persons doing intervention, outcome assessors, and/or data analysts.

20. Provide a chart summarizing participant flow, numbers and timing of randomization assignments, interventions, and measurements for each randomized group, and completeness of follow-up. Detail reasons for loss to follow-up.

21. Summarize eligibility of available data or character of ineligibles (e.g., refusal, not meeting criteria, etc.).

(Statistical Issues/Data Management)

22. State estimated effect of intervention on primary and secondary outcome measures, including a point estimate (e.g., mean, odds ratio, relative risk, etc.) and measure of precision (e.g.,
confidence interval).

23. State results in absolute numbers when feasible [e.g., 33 of 50 eyes (66%), rather than 66% alone].

24. If both eyes of each patient were studied, indicate whether they were analyzed separately or averaged, indicate what methods were used for correlated data.

25. Present summary data and appropriate descriptive and inferential statistics in sufficient detail to permit alternative analyses and calculation replication.

26. Describe prognostic variables by treatment group and any attempt to adjust for them.

27. Describe protocol deviations from the study together with the reasons/explanations.


Discussion:

29. State specific interpretation of study findings, including sources of bias and imprecision (internal validity) and discussion of external validity, including appropriate quantitative measures when possible.

30. Assess the possibility that chance accounts for any statistically significant differences between groups.

31. If "no difference" is reported, provide the power to detect a difference of meaningful clinical magnitude or provide a confidence interval for the treatment effect noted.

32. State general interpretation of the data in light of the totality of the available evidence.

33. Discuss the biological plausibility of results.

34. Discuss the clinical applications/relevance of the findings.

35. Contrast or compare the results to previous studies.

36. Discuss the need for specific additional studies if appropriate.