Study protocol

Criteria

Study protocol articles will only be considered for proposed or ongoing trials that have not completed patient recruitment at the time of submission. Please confirm the status of your study at submission.

If the study has already undergone full external peer review as part of the ethics approval or funding process, the study protocol will usually only undergo editorial peer review by the handling editor. Proof of both ethics and funding will be required, and we recommend that authors provide the relevant documentation on submission. Study protocols without major external funding will undergo full, external peer review. Study protocols without ethical approval will generally not be considered.

Protocols of randomized trials should follow the <u>SPIRIT guidelines</u>, including the SPIRIT flow diagram in the main body of the text, with the populated checklist provided as an additional file.

Preparing your manuscript

The information below details the section headings that you should include in your manuscript and what information should be within each section.

Please note that your manuscript must include a 'Declarations' section including all of the subheadings (please see below for more information).

Title page

The title page should:

- present a title that includes, if appropriate, the study design e.g.:
 - o "A versus B in the treatment of C: a randomized controlled trial", "X is a risk factor for Y: a case control study", "What is the impact of factor X on subject Y: A systematic review"
 - or for non-clinical or non-research studies: a description of what the article reports
- list the full names, institutional addresses and email addresses for all authors
 - o if a collaboration group should be listed as an author, please list the Group name as an author. If you would like the names of the individual members of the Group to be searchable through their individual PubMed records, please include this information in the "Acknowledgements" section in accordance with the instructions below
- indicate the corresponding author

Abstract

The Abstract should not exceed Yo. words. Please minimize the use of abbreviations and do not cite references in the abstract. The abstract must include the following unstructured sections:

- the context and purpose of the study (Background)
- how the study will be performed (Methods)
- a brief summary and potential implications (Discussion)
- If your article reports the results of a health care intervention on human participants, it must be registered in an appropriate registry and the registration number and date of registration should be in stated in this section. If it was not registered prospectively (before enrollment of the first participant), you should include the words 'retrospectively registered'. See our editorial policies for more information on trial registration (Trial registration)

Keywords

Three to ten keywords representing the main content of the article.

Background

The Background section should explain the background to the case report or study, its aims, a summary of the existing literature and why this case report or study was necessary or its contribution to the field.

Methods/Design

The methods section should include:

- the aim, design and setting of the study
- the characteristics of participants or description of materials
- a clear description of all processes, interventions and comparisons. Generic drug names should generally be used. When proprietary brands are used in research, include the brand names in parentheses
- the type of statistical analysis used, including a power calculation if appropriate.

Discussion

This should include a discussion of any practical or operational issues involved in performing the study and any issues not covered in other sections.

Declarations

All manuscripts must contain the following sections under the heading 'Declarations':

- Ethics approval and consent to participate
- Competing interests
- Funding
- Authors' contributions
- Acknowledgements

Please see below for details on the information to be included in these sections.

If any of the sections are not relevant to your manuscript, please include the heading and write 'Not applicable' for that section.

Ethics approval and consent to participate

Manuscripts reporting studies involving human participants, human data or human tissue must:

- include a statement on ethics approval and consent (even where the need for approval was waived)
- include the name of the ethics committee that approved the study and the committee's reference number if appropriate.

Studies involving animals must include a statement on ethics approval.

If your manuscript does not report on or involve the use of any animal or human data or tissue, please state "Not applicable" in this section.

Consent for publication

If your manuscript contains any individual person's data in any form (including individual details, images and videos), consent to publish must be obtained from that person, or in the case of children, their parent or legal guardian. All presentations of case reports must have consent to publish.

You can use your institutional consent form or our <u>consent form</u> if you prefer. You should not send the form to us on submission, but we may request to see a copy at any stage (including after publication).

If your manuscript does not contain data from any individual person, please state "Not applicable" in this section.

Acknowledgements: If necessary, gratitude must be expressed towards all people or institutions which have made any financial or technical contributions to data generation and collection.

Contributions: Authors' contributions should be cited to the following sections of the study, precisely: Study design; Data collection and analysis; Manuscript preparation.

Conflict of interest: The conflict of interest such as fees and gained or lost institutional share holdings upon paper publication must be disclosed to the editor. This will not lead to automatic rejection of the paper but we need to be informed of it. If no conflicts of interest exist, it must be declared in the form of a statement at the end of the paper saying: "The authors declare that they have no competing interests."

Funding: All sources of funding for the research reported should be declared. The role of the funding body in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript should be declared.

References: References should be numbered upon their first in-text citation, with the number in brackets before the final period. All citations should be typed in numerical order at the end of the manuscript, which, in turn, is based on the Vancouver style developed by the International Committee of Medical Journal Editors in 1944. Persian references must be translated to English and marked as [In Persian] at the end. Abbreviate names of journals should be italicized. Abbreviate names of journals according to the journal's list in PubMed is available at: (http://www.ncbi.nih.gov/sites/entrez?ab=PubMed)

References should include inverted Author(s)' surname(s) and initial(s), with a space preceding initials and a comma separating Authors' names. Avoid using "and" to separate the names.

For articles with \(\) authors or less, all names should be mentioned, but for those with more than \(\) authors, list the first three and then "et al" for the others. For unknown authors, mention the paper title instead of the author's name.

Please note that authors are responsible for the accuracy and completeness of their references.

Referencing Guidelines

Articles

Author(s)' name(s) / paper title / abbreviated Journal title (in italics) /year/volume (number)/ inclusive page numbers

Sample article citation

- Y. Lenhoff S, Hjorth M, Holmberg E, et al. Impact on survival of high—dose therapy with autologous stem cell support in patients younger than Y years with newly diagnosed multiple myeloma: a population-based study. $Blood Y \cdot \cdot \cdot ; 90(1):Y-11$.

Books

Author(s)' name(s) (or the name of the institution in charge) / book title / Volume number (if it's not the first edition) / place of publication / publisher / year of publication

Sample book citation

- 1. Adams DO, Edelson PJ, Koren HS. Methods for studying mononuclear phagocytes. San Diego, CA: Academic; 7......
- ۲. Edelaman CL, Health promotion throughout the life span. ST Louis: Mosby; ۱۹۸٤.

Chapter-in-Book

Author(s)' name(s) / chapter number / chapter title / book editors / book title / volume number (if it's not the first edition) / place of publication / Publisher / year of Publication / inclusive page numbers

Sample chapter-in-book citation

- 1. Sallan SE, Weinstein HJ. Childhood acute leukemia. In: Nathan DG, Oski FA, eds. Hematology of infancy and childhood. Vol 7. Philadelphia, PA: Saunders, 1947; pp77-77.
- 7. Philips SJ, Whisnant. Hypertension and stroke. In: Laragh JH, Brenner BM, eds. Hypertension pathophysiology, diagnosis and management. Ind ed. New York: Raven press; 1990. PP: 570-VA.

Conference paper

Presenter(s)' name(s) / paper title / compiler(s) name(s) / Conference name, date, and place / place of publication / publisher / inclusive Page numbers

Sample conference paper citation

Bengtsson S, Solheim BG. Enforcement of data protection, privacy and security in medical informatics. In: Lun KC, Degoulet P, Piemme TE, Reinhoff O, editors, MEDINFO ⁹⁷. Proceedings of the ⁹th world congress on medical informatics; ⁹⁹ sep ⁷⁻¹; Geneva, Switzerland; ⁹⁹ Amsterdam: North-Holland; ⁹⁹ P: ⁹⁹ Po ⁹⁹ P

Sample congress paper citation

- N. Mueller MC, Gattermann N, Lahaye T, et al. Dynamics of BCR-ABL mRNA transcript expression in newly diagnosed CML patients treated with imatinib or interferon alpha [abstract]. Blood ۲۰۰۲, ۱۰۰: ۳٦0a. Abstract 1517.
- ۲. Eisenberg J. Market forces and physician workforce reform: why they may not work. Paper presented at Annual Meeting of the Association of American Medical Colleges. October ۲۸, ۱۹۹۰. Washington, DC.

Dissertation (Thesis)

Author(s)' name(s) / thesis full title / Author(s)' academic level and major / university / year / number of pages.

Sample dissertation (PhD or Thesis or Masteri) citation

Kaplan SJ. Post-hospital home health care: the elderly access and utilization [dissertation]. St. Louis (Mo): Washington University 1990; PP: ۲۸.

Websites

Composer (s)' name(s) / topic / year (if available) / number of pages / website address / access date

Sample website citation

Hoffman DL. St John's Wort. 1990; [screens]. Available at URL:

http://www.healthy.net/library/books/hoffman/materiamedica/stjohns.htm. Accessed July 17, 199A.

Sample accepted but unpublished paper citation

- \. Lenhoff S, Hjorth M, Holmberg E, et al. Impact on survival of high dose therapy with autologous stem cell support in patients younger than \(\cdot \) years with newly diagnosed multiple myeloma: a population –based study. Blood. In press.
- 7. Leshner AL. Molecular mechanisms of cocaine addiction. N Engl J Med. In press.

Sample e-journal paper citation

Morsc SS. Factors in the emergence of infectious disease. *Emerg Infect Dis* [serial onlin]. \990 Jan -Mar [cited at \997]

Sample computer file citation

Hemodynamic III. The ups and downs of hemodynamics [computer programme]. Version ^۲, ⁷. Orlando (FL): Computerized Educational Systems ¹⁹⁹.

Final Confirmation

To avoid typographical errors, the article is returned to the corresponding author to be proof-read before the final submission.

Abbreviations

Conventional abbreviations should be used instead of full words. Define the abbreviated forms fully in their first in-text application. Avoid using abbreviated words in the title or abstract.

Moralities

Moralities need to be explained in the method section. It must be noted that the study was conducted with the common consent of all participants. The supporting institution of the study must also be mentioned.

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Manuscripts are checked prior to publication to ensure conformity with the style guidelines of the journal. If rejected, they will be returned without review to the corresponding author.

Once accepted by editor-in-chief or the editorial board, the paper will be refereed by three acknowledged expert authorities (reviewers) in the field.

Editorial board members will then determine whether a manuscript can be published, need revision / modification or should be rejected. Whatever the final verdict, the editorial office will let the corresponding author know as soon as possible.

Paper Retention

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