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A descriptive analytical research study in evidence-based medicine on the methodologies in clinical researches, reviews, case studies and analyses and the concepts of medical ethics

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Abstract

Clinical Research is a component of medical patient health care within Medical Sciences including Pharmacology, Clinical Pharmacology, and Evidence-Based Medicine. Clinical Research, which is intended to produce knowledge valuable for understanding human disease, preventing and treating illness, and promoting health.

Systematic Review and Meta-Analysis, the novel twins, are the two unique pillars of Clinical Research Methods in Medical Sciences including Pharmacology, Clinical Pharmacology, and Evidence-Based Medicine, that define the intricacies of the clinical study, with a maximal representation of qualitative research, review and analysis, and a minimal supplementation of quantitative analysis, in systematic review; while in meta-analysis, there remains a maximal representation of quantitative research, review and analytical interpretations. The objective of this descriptive analytical research study in Evidence-Based Medicine was to illuminate on the methodological elaborations of various Clinical Research Methods, in clinical case studies, researches, reviews and analyses, including the two most unique Methods of Clinical Research, termed Systematic Review and Meta-Analysis, and also to describe the different concepts of Medical Ethics.

Keywords: Medical Sciences, Pharmacology, Clinical Pharmacology, Evidence-Based Medicine, Clinical Research, Clinical research methods, Systematic reviews, Meta-analyses, Clinical case studies, Clinical reviews, Descriptive analysis.

Introduction

Clinical Research is a component of medical patient healthcare with in Medical Sciences including Pharmacology, Clinical Pharmacology, and Evidence-Based Medicine. Clinical Research, which is intended to produce knowledge valuable for understanding human disease, preventing and treating illness, and promoting health. Systematic Review and Meta-Analysis, the novel twins, are the two unique pillars of Clinical Research

Methods in Medical Sciences including Pharmacology, Clinical Pharmacology, and Evidence-Based Medicine, that define the intricacies of the clinical study, with a maximal representation of qualitative research, review and analysis, and a minimal supplementation of quantitative analysis, in systematic review; while in meta-analysis, there remains a maximal representation of quantitative research, review and analytical interpretations.

Objective

The objective of this descriptive analytical research study in Evidence-Based Medicine was to illuminate on the methodological elaborations of various Clinical Research Methods, in clinical case studies, researches, reviews and analyses, including the two most unique Methods of Clinical Research, termed Systematic Review and Meta-Analysis, and also to describe the different concepts of Medical Ethics.

A Descriptive Analytical Clinical Research Study

Research Methodologies and Discussion

Systematic Review and Meta-Analysis: In systematic review and meta-analysis, which are based on Evidence-Based Medicine, any or all types of original research studies, systematic reviews, meta-analyses, case reports, case series, narrative reviews, study series, parallel studies and similar kind of studies or reviews, which are either qualitative, or quantitative, or both qualitative as well as quantitative, in their description of the investigative topic, are thoroughly analysed, with statistical interpretations. After examining the relevance of the full articles, these medical data and evidences are independently obtained, using forms containing different determinant criteria of analyses, based on well-defined objectives, which are subsequently reviewed, to refine the medical database and evidences, after elaborate multi-directional assessments. The medical data and evidences are extracted from the study resources, of heterogenous qualitative or quantitative nature, or both. Studies with any or all types of study characteristics and outcomes are obtained to derive the pertinent descriptive or analytical study literature, and subsequently certain selective investigative and experimental elucidations are chosen for elaboration, from the comprehensive review compilation of the published articles, to corroborate the analytical review of the clinical research study literature, databases and evidences on the analytical topic, which finally directs itself towards a well-structured comprehensive research interpretation of the overall study results, for a final specific conclusion.

A systematic review is a detailed, systematic and transparent means of gathering, appraising and synthesising evidence to answer a well-defined question. Whereas, a meta-analysis is a statistical procedure for combining numerical data from multiple separate studies. A meta-analysis might only be conducted along a systematic review. Systematic reviews limit the bias with the use of a reproducible scientific process to search the literature and evaluate the quality of the individual studies. The results are often statistically combined into a meta-analysis in which the data are weighted and pooled to produce an estimate of effect.

Systematic Reviews are specific clinical questions, with predefined explicit methodology. These are reproducible and are the usual review of randomised controlled trials.

The systematic review protocol state objectives and eligibility criteria, identify potentially eligible studies, apply these eligibility criteria, and produced a synthesised, refined study. In meta-analysis, there are no direct comparison of patients. Summary statistics are calculated for each trial.

In a systematic review and meta-analysis, a thorough checking is done for any existing review or protocol. Then, a specific question is formulated. After that, a protocol is developed and registered. Next, a search strategy is designed. Subsequently, a literature search is conducted. Following which, studies are selected and critically appraised. Then the data is extracted and synthesised. Finally, the synthesised data is translated into study findings and interpreted. These consecutive steps of construction of a research question, scoping search, protocol devising, conducting comprehensive search, selecting studies against eligibility criteria, appraising studies using quality checklist, data extraction, results analysis, interpretation of findings, and report dissemination involve certain criteria for formulating systematic reviews and meta-analyses.

While performing these clinical research methods, during systematic reviews, after registering the protocol, the clinical questions is developed. The outlines of the research literature details inclusion and exclusion criteria. The databases to be searched are determined and the search strategy is developed. The studies reviewed and selected based on inclusion and exclusion criteria. The relevant data is extracted. The risk of bias of individual studies are assessed. The findings are summarised. The risk of bias across studies are evaluated. In meta-analyses, it is first decided, if the prospective meta-analysis is the right methodology. The research question and the eligibility criteria are defined. The protocol is written. The searching of the studies are conducted. The collaboration of study investigators is formed. The harmonisation of study population, intervention or exposure and outcome collection is done. The evidence are synthesised and the certainty of evidence are assessed. The interpretation and reporting of results are conducted. While conducting these categories of clinical research methods, the records are identified through database searching and other sources. The duplicates of the records are removed. The records are screened for relevance. From these records, certain records are excluded based on the exclusion criteria. The full text articles are assessed for eligibility. Certain full text articles are excluded with reasons for exclusion. Then, a qualitative synthesis is conducted with the included studies. Finally, the qualitatively synthesised studies are subjected to a quantitative synthesis. These processes are conducted in accordance with the PRISMA Guidelines for Systematic Reviews and Meta-Analysis. Within these guidelines and checklists, at first, the steps of identification include the records which are identified through database searching and the additional records which are identified through other sources. This leads to the steps of screening, which includes the screened records after the duplicates are removed. From these screened records, few records are excluded, as per the exclusion criteria. Then, in the eligibility step, the full text articles are assessed for eligibility, from which few full text articles are excluded, according to the exclusion criteria, with adequate reasons. This leads to the final inclusion step, where the studies are included in the qualitative synthesis or systematic review, according to the inclusion criteria, and ultimately the studies are included in the quantitative synthesis or meta-analysis.

To elaborate, a theory-based question is formulated, and scholarly works are searched for the framed questions in medical literature databases, or other valid source of scientific research. The abstract and title of the individual papers are read and relevant ones are chosen. Information from the selected final set of article is extracted. Quality of the information in the article is

determined, preferably with a suitable software or using a judgement of internal validity. The suitability of the articles is determined, statistical interpretations. The extent of the publication bias in these articles is determined, with more specific statistical analysis.

Meta-analysis has its applications in the quantitative medical, scientific and statistical research process. The advantages of systematic reviews and meta-analyses are that these limit the bias in identifying and excluding studies; these are objective and good quality evidence, which leads to more reliable and accurate conclusions; these produce more substantial results by synthesising individual study results, and these have an obvious influence over the study literature. These clinical research methods summarise evidence, thus providing the advances without reading all the published research literature. These allow large amounts of data to be assimilated. These methods give a clearer picture by collating results of research. These are explicit methods of clinical research, which allow the readers to assess how review has been compiled.

The volume of published material makes it impractical for an individual clinician to remain advanced on a variety of common conditions.

This is further complicated when individual studies report conflicting conclusions, a problem that is prevalent when due to certain bias in study methods. Meta-analysis is a set of statistical techniques from combining data from independent studies to produce a single estimate of effect. It is very often used within medical healthcare. It is used to assess the clinical effectiveness of interventions. Meta-analysis of trials provides more precise estimates of treatment effect, by making use of all available data. The validity of meta-analysis depends on the study on which it is based. Well-conducted meta-analysis aim for complete coverage of all relevant studies.

Comparative Effectiveness Research

Comparative Effectiveness Research is the generation and synthesis of evidence That compares the benefits and harms of alternative methods to prevent, diagnose, treat and monitor a clinical condition, or to improve the delivery of care.

Parallel Design or Parallel Group Study

A parallel design or a parallel group study compares two or more treatments. Participants are randomly assigned to either group, treatments are administered, and then the results are compared. It is the ‘gold standard’ for phase 3 clinical trials. Random assignment is a key element of a parallel design.

Superiority Trial

A superiority trial is designed to detect a difference between treatments. The first step of the analysis is usually a test of statistical significance to evaluate whether the results of the trial are consistent with the assumption of there being no difference in the clinical effect of the two treatments.

Non-Inferiority Trial

Non-inferiority trials aim to show that the new drug is no worse than standard treatment.

Equivalence Trials

Equivalence trials aim to show that the new treatment is no better and no worse. An equivalence boundary should be set before the trial. This is the definition of what would be the minimum important difference between the treatments.

Cluster Study

A cluster randomised trial is a study design which randomises groups of participants to each arm of a study rather than individuals.

This is done when it would be difficult to give a new treatment to an individual within a community or social group without it affecting the outcome in the standard care arm of the study.

Case-Control Study

A case-control study is a type of observational study in which two existing groups differing in outcome are identified and compared on the basis of some supposed causal attribute. Case-control studies are often used to identify factors that may contribute to a medical condition by comparing subjects who have that condition or disease, that is, the cases, with patients who do not have the condition or disease, but are otherwise similar, that is, the controls.

Cohort Study

Cohort studies are a type of longitudinal study, an approach that follows research participants over a period of time, which counts to often many years. Cohort studies recruit and follow participants who share a common characteristic, such as a particular occupation or demographic similarity.

Cross-Sectional Study

Cross-sectional study design is a type of observational study design. In a cross-sectional study, the investigator measures the outcome and the exposures in the study participants at the same time. We can estimate the prevalence of disease in cross-sectional studies.

Randomised Controlled Trials

Randomised controlled trials are prospective studies that measures the effectiveness of a new intervention or treatment. Although no study is likely on its own to prove causality, randomisation reduces bias and provides a rigorous tool to examine cause-effect relationships between an intervention and outcome.

This is because the act of randomisation balances participant characteristics (both observed and unobserved) between the groups allowing attribution of any differences in outcome to the study intervention.

Uncontrolled Trials

This design incorporates no control arm. This design is usually utilised to determine pharmacokinetic properties of a new drug (phase I trials). Uncontrolled trials are known to produce greater mean effect estimates than a controlled trial, thereby inflating the expectations from the intervention. There is a threat of inherent bias and results are considered less valid than randomised controlled trials.

Decision Analytical Study

Decision analysis is a tool that allows users to apply evidence-based medicine to make informed and objective clinical decisions when faced with complex situations. A decision-maker can thereafter establish a preferred method of treatment and explore variables which influence the final outcome.

Genetic Association Study

A genetic association study aims to test whether a given sequence, such as a region of a chromosome, a haplotype, a gene, or an allele, has involvement in controlling the phenotype of a specific trait, metabolic pathway, or disease.

Evidence-Based Medicine

Evidence-Based Medicine (EBM) is the combination of the best available research evidence with clinical experience and patient needs. The concept of EBM as a part of clinical decision making has become increasingly popular over the last decade. In the hierarchy of studies meta-analysis and systematic reviews occupy the highest levels. A systematic review of a clinical question can be performed by following a relatively standard form.

Systematic reviews conducted in this fashion can be used as a higher form of current concepts or as review articles and replace the traditional expert opinion narrative review.[1, 2]

Medical Ethics

Medical Ethics is an inherent and inseparable part of clinical medicine, as the physician has an ethical obligation (i) to benefit the patient, (ii) to avoid or minimise harm, (iii) and to respect the values and preferences of the patient. Medical ethics is concerned with the nature of morals, the specific moral choices to be made, and the accepted general moral norms of guidance and evaluation for right professional conduct and codes, transcending different group identities, in medical practice and medical research, in the form of research ethics, public health ethics, organisational ethics and clinical ethics. The goals of medical ethics are to appreciate ethical dimensions of patient care, to understand ethical principles of medical profession, to have competence in core ethical behavioural skills, including obtaining informed consent, assessing decision-making capacity, discussing resuscitation status, and use of life-sustaining treatments, advanced care planning, medical worse prognosis information, and effective medical communication, to know the commonly encountered ethical issues in general and in one's own speciality, to have competence in analysing and resolving ethical problems, and to appreciate cultural diversity and its impact on medical ethics.

Conclusion

This research study well-elaborates about the clinical research methods and their applications in Pharmacology, Clinical Pharmacology and Evidence-Based Medicine, while also specifically illuminating on the comprehensive clinical significance of systematic reviews and meta-analyses. This study even describes certain details about the various prevailing concepts of medical ethics, in medical practice and research.

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