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A Comprehensive Review of Clinical Trial Design

Sakshi Ambilwade*

Sandip Institute of Pharmaceutical Science, Nashik, Maharashtra, India.

Abstract

In clinical research, research study design is defined as a plan, protocol, method, or strategy of a study. Clinical study designs are useful in finding the efficacy and concern of the drugs and disease. The purpose of this review article is to provide an overview of the study design in clinical research. The purpose of the study is based on study design. The research study design is classified into two types, observational study, and interventional study and both studies are again classified into different types. Observational study is completed more quickly than interventional study. Every study has advantages and disadvantages in terms of money and time.

Keywords: clinical trial; study design; observational; interventional; experimental

Introduction

Study designs are used to identify the reason for disease, use of drugs, and drug effects. Study design is a plan, protocol, and strategy of a study. To improve patient care new drugs, enter in market with unknown effects. To find out the unknown cause of disease and the effect of the drug research study design was used. Well, a well-designed study can minimize the errors. The aim of this review article is to describe the concept of study design [1].

Types of Study

Design

Research study designs are classified into two types: Observational study design: In observational study design, the trial subject or participant involved in the trial is just observed. The name itself shows that no interventions are included. Based on the time, observational study is again classified into two types i.e. analytical and descriptive study. Descriptive studies generate hypotheses in other analytical studies to test hypotheses and experimental study helps to prove the hypotheses. Observation study asks the questions like who, where, and when. There is other study design that comes under the descriptive and analytical study including cohort, case-control, cross-sectional, case report, case series, and survey [2].

Analytical study

Cohort study

Cohort study is the study design that is used to compare two groups., i.e. subject with risk factor or subject without risk factor. This study was also used to determine the causal relationship between the risk and outcome. Cohort study classified as prospective or retrospective studies. A prospective cohort study follows the subject from the presence of risk factors to the development of the disease which is why it is time time-consuming and expensive study to conduct. Retrospective studies identify a patient with or without the risk factor based on their past medical records [3].

Case-control study

Case-control study is the opposite of cohort study which means this study starts with the outcome and searches for the risk factors from records. This study compares people with the disease (case) and people without the disease (controls). Case-control studies require less time and minimum cost to conduct the study. It may be susceptible to bias because to outcome is not known to be appropriate to use [4].

Cross-sectional study

A cross-sectional study measures the risk factor and outcome at the same time on the population. It simply means asking questions and getng the answer to risk factors and outcomes. Follow-up is not needed in this type of study. This study can conduct through surveys, analysis, or reviews. The advantages of cross-sectional study are that the data can be available easily, fast and this study is not expensive. This study is not suitable for the acute disease population or it is susceptible to bias and causality cannot be determined [5].

Descriptive study

Case report

The case report is the patient's experience with drug exposure and the outcome of drug exposure in the

patient. The case report is used to set the hypothesis. Case reports give details on adverse drug reactions and rare diseases.

Case series

Case series simply means the collection of case report forms of the patient who has the risk factor and the same outcome of the treatment. Case series are useful for finding adverse drug reactions. More case reports with common events strengthen the conformation of the case. Surveys: Survey means the collection of information from a group of a population. Various types of information include demographics, attitudes, characteristics, knowledge, and behaviors. Surveys can do face-to-face, telephonic, postal, web surveys, etc. Collect the information by asking the question [9]. Experimental study design: In an experimental study, there is an intervention involved. i.e. this study design is also called an interventional study design. Intervention may be a drug or device that participants receive according to the research plan that is created by the investigators. Experimental study design is classified based on randomization. i.e. randomized and non-randomized study [11]. Randomized study: A randomized clinical trial study design involves the subject randomly to the two groups. i.e. the group that receives intervention and other the group that receives the placebo. This randomized study design can be performed by using computer software or other methods. This type of study design reduces the bias [7,10].

Non-randomized study

A non-randomized study design involves subject selection without randomization. This study contains bias regarding the subject selection. Nonrandomized study design is fast, easy to use, and less costly [7].

Conclusion

We have discussed the various clinical study designs in this review article. Appropriate participant selection and randomization strategy are paramount. Ensuring ethical considerations, regulatory compliance and statistical consideration enhance the trials credibility. A well-designed clinical trial not only strengthens the scientific validity but also facilitates the accurate interpretation of results and contributes to medical knowledge and patient care.

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