JETIR.ORG ISSN: 2349-5162 | ESTD Year : 2014 | Monthly Issue
JOURNAL OF EMERGING TECHNOLOGIES AND INNOVATIVE RESEARCH (JETIR)
An International Scholarly Open Access, Peer-reviewed, Refereed Journal

An over view on Bias in Clinical research studies

[1]Javed Ali Khan, [2]Pathan Jamal Khan
[1] National Research Institute
of unani medicine for skin disorders
,Hyderabad , Telengana state, Hyderabad- 38
[2] Ex HOD at Orata University , South Africa

Abstract : The aim of the article is to outline types of "bias" in clinical research studies and consider strategies to minimize bias. In the article various types of bias starting from the designing of the study to publication of the study are discussed. However major types of bias are discussed. Bias can occur in planning, data collection, analysis and publication. This article aims at minimizing the bias at different stages of clinical trials which may be useful to clinical researchers and Medical students who are into clinical research. A thorough understanding of bias and how it effects clinical study and results is essential for the practice of evidence – based medicine.

I. INTRODUCTION

II. Definition of bias

Bias is the tendency to overestimate or underestimate a phase of a clinical trial, parameter. Bias is not a dichotomous variable. Interpretation of bias cannot be limited to a simple inquisition. Bias impacts on the validity and reliability of study findings and misinterpretation of data can lead to more bias in the research study.

Bias in sample size estimation

Bias in sample size estimation occurs due to errors in estimation of sample size which can be minimized by applying correct formula and getting the correct and authentic prevalence or statistical findings of the clinical research study to be initiated. Estimation of sample size plays a important role in clinical research trails. Sample size of a study plays a vital role in the outcome of the study.

Bias in selecting proper study design

Bias in study design occurs while selecting the study design, this can be avoided by selecting proper study design which is suitable to the study such as open label study, single blind study, double blind study and triple blind study.

Bias in randomization

Bias in randomization occurs while selecting a proper randomization method. A proper randomization method such as simple random sampling, stratified random sampling, Cluster sampling and other types of random sampling methods. Random sampling plays an important role in clinical research trails by equal distribution of patients in either groups by age ,sex and chronicity and other parameters which are essential for an unbiased outcome of the clinical research trail.

Bias in selection

Bias in selection occurs during the selection of patients via inclusion and exclusion criteria of the particular clinical research trail of the respective protocol of the study This can be minimized by fixing a proper inclusion and exclusion criteria and proper interviewing of the patients by the concerned physician and concerned paramedical staff dealing with the patient. The patients should be well counseled regarding all the details of the clinical research study so that effective out comes can be achieved.

Bias in recording clinical research data

Bias in in recording clinical research data occurs in various forms a few are highlighted here. For instance, we are recording the data of 30 patients before and after treatment all the clinical, pathological and biochemical findings of each patient before and after treatment should be recorded in the CRF. If some on the data in either before and after treatment is missing, then in effects the outcome of the study. The clinical, pathological and biochemical findings of the patients should be recorded in a uniform pattern for instance body weight of patients are recorded in terms of pounds before treatment, after treatment also it should be recorded in terms of pounds, if its recorded in terms of Kgs and wise versa then the outcome of the study will be biased.

Bias in Statistical Analysis of Clinical research data

This can occur when the statistician analyzing the data is not aware of the parameters which are to be highlighted such as safety parameters and those parameters which effect the efficacy of the drug. This can be avoided by giving proper input to the statistician regarding safety parameters and the parameters which effect efficacy of the drug by the Principle investigator of the respective clinical research study. Proper tabulation, correlation and graphical representation of clinical, pathological and biochemical parameters would give a clear picture of the research study. In some instances, a particular value of a parameter may be statistically significant but it may not be clinically significant and wise versa. A good communication between all the medical and paramedical staff involved in the clinical research study may reduce the above bias to maximum extent.

Bias in publication

This can occur while we are publishing the research article without selecting and highlighting the parameters and important details pertaining to clinical research study for instance duration of the study , Dosage and administration of the drug , methodology , results and discussion , source of funding, place of initiation of the study and proper references would reduce the publication bias to considerable extent.

Here in the table 1 you can see the specific name of the bias , group of bias , subgroup of bias specific name of bias and type of design affected with the bias.

Table 1 Alphabetical list of biases, indicating their type and the design where they can occur

Specific name of bias	Group of bias	Subgroup of bias (next level to specific name)	Type of design affected
Allocation of intervention bias	Execution of an intervention		Trial
Apprehension bias	Information bias	Observer bias	All studies
Ascertainment bias	Selection bias	Inappropriate definition of the eligible population	Observational study
Berkson's bias	Selection bias	Inappropriate definition of the eligible population	Hospital based case-control study
Centripetal bias	Selection bias	Healthcare access bias	Observational study
Citation bias	Selection bias	Lack of accuracy of sampling frame	Systematic review/meta-analysis
Competing risks	Selection bias	Ascertainment bias	All studies
Compliance bias	Execution of an intervention		Trial
Confounding by group	Confounding		Ecological study
Confounding by indication	Confounding		Case-control study, cohort study
Contamination bias	Execution of an intervention		Trial, mainly community trials
Detection bias	Selection bias	Uneven diagnostic procedures in the target population	Case-control study
Detection bias	Information bias	Misclassification bias	Cohort study
Diagnostic/treatment access bias	Selection bias	Healthcare access bias	Observational study
Diagnostic suspicion bias	Selection bias	Detection bias	Case-control study
Diagnostic suspicion bias	Information bias	Detection bias	Cohort study
Differential maturing			Trial
Differential misclassification bias	Information bias	Misclassification bias	All studies
Dissemination bias	Selection bias	Lack of accuracy of sampling frame	Systematic review/meta-analysis
Ecological fallacy	Information bias		Ecological study
Exclusion bias	Selection bias	Inappropriate definition of the eligible population	Case-control study
Exposure suspicion bias	Information bias	Recall bias	Case-control study
Family aggregation bias	Information bias	Reporting bias	Observational study
Friend control bias	Selection bias	Inappropriate definition of the eligible population	Case-control study
Hawthorne effect	Information bias		Trial
Healthcare access bias	Selection bias	Ascertainment bias	Observational study
Healthy volunteer bias	Selection bias	Non-response bias	Observational study
Healthy worker effect	Selection bias	Inappropriate definition of the eligible population	Cohort study (mainly retrospective)
Incidence-prevalence bias (synonym of Neyman bias)			
Inclusion bias	Selection bias	Inappropriate definition of the eligible population	Hospital based case-control study
Lack of intention to treat analysis			Randomised trial
Language bias	Selection bias	Inappropriate definition of the eligible population	Systematic review/meta-analysis
Lead-time bias	Information bias		Screening study
Length biased sampling	Selection bias	Ascertainment bias	Cross sectional study, screening
Losses/withdrawals to follow up	Selection bias	During study implementation	Cohort study, trial
Mimicry bias	Selection bias	Detection bias	Case-control study
Mimicry bias	Information bias	Detection bias	Cohort study
Misclassification bias	Information bias		All studies
Missing information in multivariable analysis	Selection bias	During study implementation	All studies (mainly retrospective)
Mode for mean bias	Information bias	Reporting bias	All studies
Neyman bias	Selection bias	Ascertainment bias	Cross sectional study, case-control study with prevalent cases
Non-differential misclassification bias	Information bias	Misclassification bias	All studies
Non-random sampling bias	Selection bias	Lack of accuracy of sampling frame	Observational study
Non-response bias	Selection bias	During study implementation	Observational study
Obsequiousness bias	Information bias	Reporting bias	All studies
Observer expectation bias	Information bias	Observer bias	All studies
Observer/interviewer bias	Information bias	Misclassification bias	All studies
Overmatching	Selection bias	Inappropriate definition of the eligible population	Case-control study
Participant expectation bias	Information bias	Recall bias	Trial
Popularity bias	Selection bias	Healthcare access bias	Observational study
Post hoc analysis	Selection bias	Publication bias	Systematic review/meta-analysis
Protopathic bias	Information bias		Observational study
Publication bias	Selection bias	Lack of accuracy of sampling frame	Systematic review/meta-analysis
Purity diagnostic bias	Selection bias	Spectrum bias	Validity of diagnostic tests
Recall bias	Information bias	Misclassification bias	All studies
Referral filter bias	Selection bias	Healthcare access bias	Observational study
Regression dilution bias	Information bias	Regression to the mean	Cohort study, trial
Regression to the mean	Information bias		Cohort study, trial
Relative control bias	Selection bias	Inappropriate definition of the eligible population	Case-control study
Reporting bias	Information bias	Misclassification bias	All studies
Rumination bias	Information bias	Recall bias	Case-control study, retrospective cohort study

Table 1 Continued

Specific name of bias	Group of bias	Subgroup of bias (next level to specific name)	Type of design affected
Selective survival bias (synonym of Neyman bias)			
Sick quitter bias	Information bias	Protopathic bias	Observational study
Spectrum bias	Selection bias	Ascertainment bias	Validity of diagnostic tests (mainly case-control study)
Survivor treatment selection bias	Selection bias	Ascertainment bias	Cohort study (mainly retrospective)
Susceptibility bias (synonym of confounding)			
Telephone random sampling bias	Selection bias	Non-random sampling bias	Observational study
Temporal ambiguity	Information bias		Cross sectional study, ecological study
Unacceptable disease/exposure	Information bias	Reporting bias	Observational study
Underreporting bias	Information bias	Reporting bias	Observational study
Unmasking—detection signal—bias	Selection bias	Detection bias	Case-control study
Verification bias (synonym of work up bias)			
Will Rogers phenomenon	Information bias		Prognostic (mainly cohort) study
Work up bias	Information bias		Validity of diagnostic test (retrospective study)

Bibliography

1 Rothman K, Greenland S. Modern epidemiology. 2nd ed. Boston: Lippicontt-Raven, 1998.
2 Kleinbaum DG, Kupper LL, Morgenstern H. Epidemiologic research. Belmont,CA: Lifetime Learning Publications, 1982.
3 Sackett DL. Bias in analytic research. J Chron Dis 1979;32:51–63.
4 Choi BCK. Bias, overview. In: Gail MH, Benichou J, eds. Encyclopedia ofepidemiologic methods. Chichester: Wiley, 2000:74–82.
5 Maclure M, Schneeweiss S. Causation of bias: the episcope. Epidemiology2001;12:114–22.
6 Steineck G, Ahlbom A. A definition of bias founded on the concept of the studybase. Epidemiology 1992;3:477–82.7 Ellenberg JH. Selection bias in observational and experimental studies. Stat
Med 1994;13:557–67.
8 Kleinbaum DG, Morgenstern H, Kupper LL. Selection bias in epidemiologicstudies. Am J Epidemiol 1981;113:452–63.
9 Greenland S. Basic methods for sensitivity analysis of biases. Int J Epidemiol1996;25:1107–16.
10 Pollock AM, Benster R, Vickers N. Why did treatments rates for colorectalcancer in south east England fall between 1982 and 1988? The effect of caseascertainment and registration bias. J Public Health Med 1995;17:419–28.
11 Chiang CL. Competing risks in mortality analysis. Annu Rev Public Health1991;12:281–307.
12 Gail M. Competing risks. In: Kotz S, Johnson NL, eds. Encyclopedia of
statistical sciences. Vol 2. New York: Wiley, 1982:75–81.
13 Simon R. Length biased sampling in etiologic studies. Am J Epidemiol1980;111:444–52.
14 Neyman J. Statistics: servant of all sciences. Science 1955;122:401–6.
15. 58 Maldonado G, Greenland S. Estimating causal effects. Int J Epidemiol2002;31:422–9.
16.59 Greenland S, Brumback B. An overview of relations among causal modellingmethods. Int J Epidemiol 2002;31:1030–7.