ORIGINAL RESEARCH PAPER
Volume - 10 | Issue - 02 | February - 2021 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

RADIATION ONCOLOGIST PROSPECTIVE OF CLINICAL TRIALS AND STUDIES IN ONCOLOGY

Oncology

Mirza. Baig* Associate Professor department of Radiation oncology, MLB Medical College Jhansi. *Corresponding Author

Kumar. Dev Assistant professor department of Radiation oncology, MLB Medical College Jhansi.

ABSTRACT

Clinical trials are research studies performed in people that are aimed at evaluating a medical, surgical, or behavioral intervention .They are the primary way that researchers find out if a new treatment, like a new drug or diet or medical device is safe and effective in the people often a clinical trial is use to learn if a new treatment is more effective and or has less harmful side effects than the standard treatment.

KEYWORDS

Clinical trials, Research, Drugs.

Discussion –

Measurement of treatment response in oncology –

A- Complete response – complete disappearance of all evidence disease, and no new lesion or disease related symptoms.

B- **Partial response** – after treatment 25% to 50% regression in size of tumor (sum of product of perpendicular diameter of all measurable lesions) without any new lesion is called partial response.

C- Progressive disease - less than 25% of objective response in size of tumor either by radiotherapy or chemotherapy considered as progressive lesion.

D- Recurrence of disease – tumor after complete disappearance appeared after six month of treatment called as recurrent lesion.

E- Residual disease – presence of disease at the end treatment or recurrence within six month of treatment called as residual disease.

F- Overall survival – time of first day of treatment up to the death of patient owning to any cause called overall survival.

G- Disease free survival – time of first day of treatment to the recurrence of disease called as disease free survival.

Phases of clinical trials –

Phase -1 trail – This type of trail perform on very less number of patients after taking consent of patient and approval of institute ethical committee to determine both toxicity profile of particular type of drug or treatment as well as determine the effect of drug on body that is pharmacodynamics , and also to find out effect of body on the drug that is pharmacokinetics , ideally 20 to 80 patients are selected for this trail .

Phase-2 trail – Data available from phase -1 trial to treat a selected group of patients to determine toxicity of particular type of treatment and its effects on cancer or tumor.

Phase -3trail – It compare the particular method of treatment or drug result of phase 2 trial Vs currently available standard of care treatment ,this study being perform on large number of patients .

Phase -4 trails - A type of clinical trial that studies the side effects caused over the time by new treatment after it has been approved and is on market, phase 4 trials may includes many thousands of patients, It is also called as post-marketing surveillance trail.

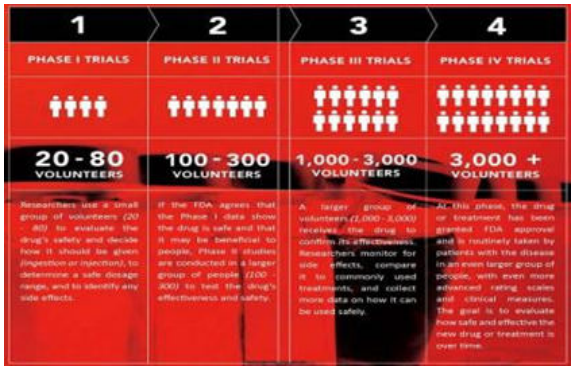

Figure -1 Phase of trials

Please note – for any stage of clinical trial consent of patient and approval by ethical committee is must.

A-Randomized control trial –

Randomized control trial is the number method of evaluation of particular type of treatment and its response evaluation , in this study we do random allocation, and randomization , randomization is a statical procedure by which the participants are allocated in two groups first is study group second is control group , study group received particular method of treatment as per protocol and control group not to received treatment , basically randomization is an attempt to eliminate selection bias it's also allow every individual to get equal chance of being evaluated either in test group or in control group.

The basic steps involved in conducting Randomized control trial are –

1- Designing a protocol.
2- Selection of test and control group.
3- Process of doing randomization.
4- Intervention (Treatment)
5- Follow up.
6- Assessment of out of study (Result).

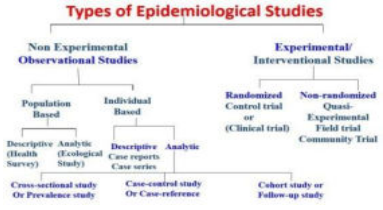

Figure -2, How we design studies

B- Non Randomized control trial.

Those patients drop out due to strict randomization process for practical purposes but in such a manner that Non randomization does not seriously affect the theoretical basis of result or conclusion.

Reasons for Non Randomized control trial.

1- It's not always possible for ethical or administrative and other reasons to restart randomized control trial on human beings, for example smoking and lung cancer and induction of cancer by viruses have not let it done on direct experiments on human being.
2- Some preventive measures can applied on only study groups or community basis.
3- When the disease frequency is low and their natural history is very long like cervical cancer here randomized control trial require very long follow up for thousands of people for a decade or more henceforth we prefer Non randomized control trial.

Meta analysis – Evidence after analysis obtained from multiple randomized control trails on same treatment policy (same study) from different research institute called Meta analysis.

Figure -3, Stepping up for Meta analysis.

Incidence of disease?

Defined as the number of new cases occurring in a defined population during a specified period of time**.**

Prevalence of disease –

Defined as all current (old and new) cases existing at a given point of time .

Measurement of Disease-

It's mandatory to have clear cut picture of amount of disease burden on population, the information and data can be obtained by finding out, mortality rate, morbidity rate, disability rate for that incidence rate can be obtained by longitudinal studies, and prevalence can be obtained by cross sectional studies.

A-Cross Sectional studies-

It's a simplest form of observational studies, it's based on a single examination of a cross section of a specified population at a given point of time, since cross sectional studies data obtained by the help of prevalence rate henceforth this study also known as prevalence study, such study tell us about distribution of disease in a specified population in a given time but did not tell us about the risk factor or etiology of disease in population.

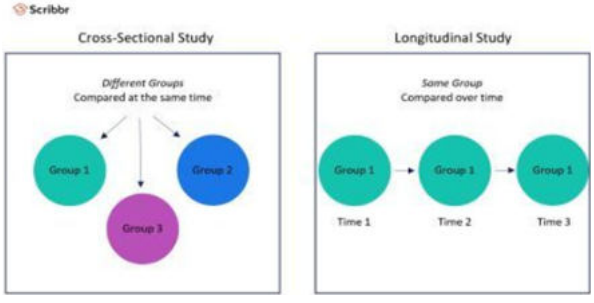

Figure-4, Designing of Cross sectional and longitudinal studies.

B- Longitudinal studies-

Basically cross sectional studies is like one single snap shot photograph but longitudinal studies is like full cine film.

Longitudinal studies useful as

1- Study of natural history of disease and its outcome.
2- Identifying the risk factor of disease.
3- Finding out incidence rate of disease.

Longitudinal studies provides us valuable information which cross sectional studies do not provide , but longitudinal studies are difficult to organize and more time consuming than cross sectional studies .

Analytical studies –

Analytical studies are second major type of epidemiological studies, in analytical studies the subject of interest is although here individual with in the population are evaluated but the inference drawn not only for that individual but to the population from which they were selected.

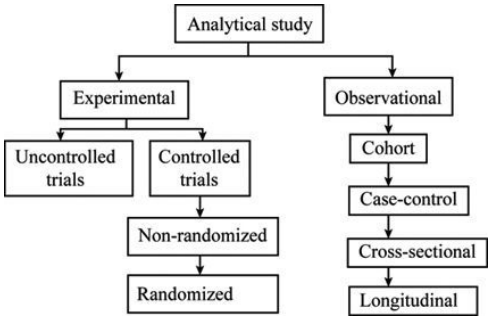

Figure -5, Analytical study steps.

Analytical studies are of two types –

1- Case control study.
2- Cohort study.

By both the studies we can determine two things, one is statical association exists between disease and suspected risk factor other one is if risk factor is Identified what is the strength of its association between risk factor and disease.

Case control study (Retrospective study) –

Often called as retrospective studies, this study emerged as permanent method of epidemiological investigation, case control studies having three important features.

1- Both exposure and outcome (disease) have occurred before the start of disease.
2- Study proceed effect (outcome) to cause

By definition case control studies have two arms one is case other is control , so case control studies conducted on disease that is already developed ,for example one can considered cases(immunized) ,and control (unimmunized) one .

Odds ratio –

From case control study we can find out odds ratio which measures the strength of association between risk factor and outcome (disease).

We calculate odds ratio like

	Disease	
	Yes	No
Expose	A	B
Unexposed	C	D

Odds ratio = A×D/B×C.

Advantages of case control studies –

1- Relatively easy to carry out
2- Rapid result and inexpensive
3- Suitable for rare disease about nothing more known so for.
4- No risk to the subjects upon which studies carried out.
5- No Ethical problems.
6- Risk factor can be identified in order to take preventive and control measure.

Disadvantages of case control studies –

1- We cannot measure the incidence rate of disease.
2- Not suitable for evaluation of therapy or prophylaxis of disease.

Cohort studies (Prospective study)–

Cohort studies also known as prospective studies or incidence studies or forward looking studies we know this study under two heads

1- Cohorts are identified prior to the appearance of disease under study
2- Study proceeds forward from cause to effect.

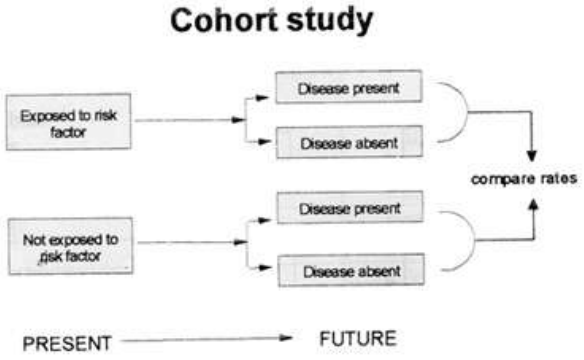

Figure -6, Steps of Cohort study.

So cohort study is always superior to case control study, also cohort study carried out larger number of population in compare to case control study, but cohort study is expensive in comparison to case control study.

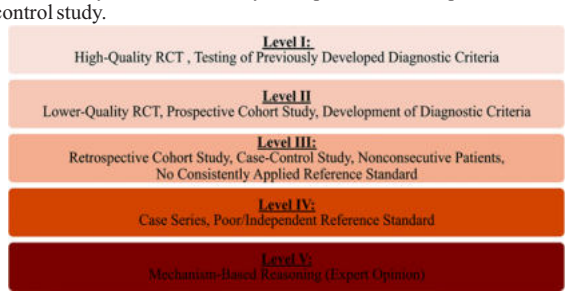

Figure -7, Level of Evidence of studies and trials

REFERENCES

1. Streptomycin treatment of pulmonary tuberculosis: a Medical Research Council investigation. BMJ 1948;2:769-782
2. .Byar DP, Simon RM, Friedewald WT, et al. Randomized clinical trials: perspectives on some recent ideas. N Engl J Med 1976;295:74-80
3. Feinstein AR. Current problems and future challenges in randomized clinical trials. Circulation 1984;70:767-774
4. Abel U, Koch A. The role of randomization in clinical studies: myths and beliefs. J Clin Epidemiol 1999;52:487-497
5. Sacks H, Chalmers TC, Smith H Jr. Randomized versus historical controls for clinical trials. Am J Med 1982;72:233-240
6. Evidence-Based Medicine Working Group. Evidence-based medicine: a new approach to teaching the practice of medicine. JAMA 1992;268:2420-2425
7. Preventive Services Task Force. Guide to clinical preventive services: report of the U.S. Preventive Services Task Force. 2nd ed. Baltimore: Williams & Wilkins, 1996.
8. Schulz KF, Chalmers I, Hayes RJ, Altman DG. Empirical evidence of bias: dimensions of methodological quality associated with estimates of treatment effects in controlled trials. JAMA 1995;273:408-412
9. Horwitz RI, Viscoli CM, Clemens JD, Sadock RT. Developing improved observational methods for evaluating therapeutic effectiveness. Am J Med 1990;89:630-638
10. Horwitz RI, Feinstein AR. Methodologic standards and contradictory results in case-control research. Am J Med 1979;66:556-564