A Review - Clinical Research And Clinical Trials

Sanket Dandnaik[1*], Ankita Gadhawe[2], Dr.H.V.Kamble[3], Santosh Waghmare[4], Ashwini Andhale[5]
[3, 4, 5] Faculty
[1, 2, 3, 4, 5] LSDP college of pharmacy, Mandgavan Pharata, Tal- Shirur, Dist- Pune.

Abstract- *For most clinical research abstracts, the following areas are specifically mentioned: research design; research setting; number of patients enrolled in the study and how they were selected; a description of the intervention (if appropriate); and a listing of the outcome variables and how they were measured. Clinical trials/research are conducted to examine the clinical questions of practicing physicians. It is important to design trials appropriately in advance, taking their feasibility into account. A randomized, controlled trial is the ultimate design for treatment comparisons at the final confirmatory stage.*

Keywords- Clinical trials , Phases, research ,Randomization

I. INTRODUCTION

Research in which people, or data or samples of tissue from people, are studied to understand health and disease. Clinical research helps find new and better ways to detect, diagnose, treat, and prevent disease.[1]

What is Clinical Research...?

- Clinical research is the study of health and illness in people.
- It is the way we learn how to prevent, diagnose and treat illness.
- Clinical research describes many different elements of scientific investigation.
- It involves human participants and helps translate basic research (done in labs) into new treatments and information to benefit patients.
- Clinical trials as well as research in epidemiology, physiology and pathophysiology, health services, education, outcomes and mental health can all fall under the clinical research umbrella[2]

Clinical Trials

- A clinical trial is a type of clinical research study.
- A clinical trial is an experiment designed to answer specific questions about possible new treatments or new ways of using existing (known) treatments. Clinical trials are done to determine whether new drugs or treatments are safe and effective.
- Clinical trials are part of a long, careful process which may take many years to complete. First, doctors study a new treatment in the lab. Then they often study the treatment in animals.
- If a new treatment shows promise, doctors then test the treatment in people via a clinical trial.[3]

Clinical research and medical care

- People often confuse a clinical research or clinical trials with medical care. This topic can be especially confusing if your doctor is also the researcher.
- When you receive medical care from your own doctor, he or she develops a plan of care just for you.
- When you take part in a clinical research study, you and the researcher must follow a set plan called the "study protocol." The researcher usually can't adjust the plan for you – but the plan includes steps to follow if you aren't doing well.
- It's important to understand that a clinical trial is an experiment. By its nature, that means the answer to the research question is still unknown.
- You might or might not benefit directly by participating in a clinical research study. It is important to talk about this topic with your doctor/the researcher.[4]

II. TYPES OF CLINICAL RESEARCH

Different types of clinical research are used depending on what the researchers are studying. Below are descriptions of some different kinds of clinical research.

- **Treatment Research** generally involves an intervention such as medication, psychotherapy, new devices, or new approaches to surgery or radiation therapy.
- **Prevention Research** looks for better ways to prevent disorders from developing or returning. Different kinds of prevention research may study medicines, vitamins, vaccines, minerals, or lifestyle changes.
- **Diagnostic Research** refers to the practice of looking for better ways to identify a particular disorder or condition.

- **Screening Research** aims to find the best ways to detect certain disorders or health conditions.
- **Quality of Life Research** explores ways to improve comfort and the quality of life for individuals with a chronic illness.
- **Genetic studies** aim to improve the prediction of disorders by identifying and understanding how genes and illnesses may be related. Research in this area may explore ways in which a person's genes make him or her more or less likely to develop a disorder. This may lead to development of tailor-made treatments based on a patient's genetic make-up.
- **Epidemiological studies** seek to identify the patterns, causes, and control of disorders in groups of people.

An important note: some clinical research is "outpatient," meaning that participants do not stay overnight at the hospital. Some is "inpatient," meaning that participants will need to stay for at least one night in the hospital or research center. Be sure to ask the researchers what their study requires.[5]

Examples of other kinds of clinical research

Many people believe that all clinical research involves testing of new medications or devices. This is not true, however. Some studies do not involve testing medications and a person's regular medications may not need to be changed. Healthy volunteers are also needed so that researchers can compare their results to results of people with the illness being studied. Some examples of other kinds of research include the following:

- A long-term study that involves psychological tests or brain scans
- A genetic study that involves blood tests but no changes in medication
- A study of family history that involves talking to family members to learn about people's medical needs and history.[6]

Phases of clinical trials:

Clinical trials are a kind of clinical research designed to evaluate and test new interventions such as psychotherapy or medications.

Clinical trials are often conducted in four phases. The trials at each phase have a different purpose and help scientists answer different questions.

- **Phase I trials**
  Researchers test an experimental drug or treatment in a small group of people for the first time. The researchers evaluate the treatment's safety, determine a safe dosage range, and identify side effects.
- **Phase II trials**
  The experimental drug or treatment is given to a larger group of people to see if it is effective and to further evaluate its safety.
- **Phase III trials**
  The experimental study drug or treatment is given to large groups of people. Researchers confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the experimental drug or treatment to be used safely.
- **Phase IV trials**
  Post-marketing studies, which are conducted after a treatment is approved for use by the FDA, provide additional information including the treatment or drug's risks, benefits, and best use.[7]

III. WHAT HAPPENS IN DIFFERENT PHASES OF CLINICAL TRIALS?

Phase I clinical trials

Doctors do a phase I clinical trial to learn if a new drug, treatment, or treatment combination is safe for people. They may have already tested it in laboratory animals.

In a phase I clinical trial, doctors collect information on:

- The dose or treatment
- When you take it, and how often
- Any side effects or problems
- How the treatment affects you, such as how it affects the cancer or side effects

In a phase I clinical trial, you could be one of the first people to get the new drug or treatment.

Phase I clinical trials each last several months to a year. They usually have 10 to 30 volunteers. The treatment might help the cancer. Also, information from the clinical trial may help other people in the future.[8]

Phase II clinical trials

A phase II clinical trial tells doctors more about how safe the treatment is and how well it works. Doctors also test

whether a new treatment works for a specific cancer. They might measure the tumor, take blood samples, or check how well you can do certain activities. Or you might keep a log of your daily activities and symptoms. These are all ways to learn how well the treatment works.

A Phase II clinical trial lasts about 2 years. Volunteers sometimes receive different treatments. For example, a phase II trial could have 2 groups.

- Group 1 – People who receive the usual treatment for the condition. This is also called the standard treatment. It is the best treatment known.
- Group 2 – People who receive the usual treatment plus the new treatment doctors are studying.

Or a phase II clinical trial could have 3 groups. Volunteers in each group get a different dose of the treatment doctors are studying.

If the phase II clinical trial shows the treatment works and is as safe as the regular treatment, doctors can do a phase III trial.

How do doctors put volunteers into groups in a clinical trial?

- Doctors use a computer program to put volunteers into different groups.
- The computer does this at random, which means by chance.
- Each volunteer has an equal chance of going in any of the groups. The name for this process is "***Randomization***."
- Using a computer to put volunteers in groups keeps the research staff from possibly changing the clinical trial results.
- They might do this if they chose who went in which group. For example, they might think a certain volunteer would benefit from the new treatment. So they might put that person in the new-treatment group. But this could change the clinical trial results. Randomization helps avoid this.
- It is very important to use randomization when a clinical trial compares 2 treatments or more.

Phase III clinical trials

- A phase III clinical trial tests a treatment that worked well for volunteers in a phase II clinical trial. Doctors use phase III to compare the new treatment with the standard treatment. They want to know if the new treatment is better, has fewer side effects, or both. So they put volunteers in different groups. The volunteers in each group get a different treatment.
- Phase III clinical trials can take many years. They may have several thousand volunteers. These must include men, women, and people of different ages and ethnic groups, if possible. **Thishelps doctors learn how the treatment works in different people.**
- If a phase III clinical trial shows the treatment works well, doctors might begin using it with people outside the clinical trial. For example, if they learn that a certain amount of exercise lowers your cancer risk, they publish a report. This shares the information with other doctors. If the researchers or sponsor learn a new medicine is safe and effective, they can ask the government to approve it for people to use. In the United States, they ask the Food and Drug Administration (FDA). The FDA looks at the results of the clinical trial's phases. They approve the treatment if the results meet their standards

Phase IV clinical trials (Post Marketing)

- Doctors can prescribe a drug for their patients after the FDA approves it. But the FDA may require the sponsor to keep studying that approved treatment.
- In these clinical trials, doctors may check if the treatment benefits people as much as it did earlier. They also look for more possible side effects. These clinical trials are called phase IV clinical trials.
- In a Phase IV clinical trial, doctors might study the drug or treatment in different doses, or with other drugs or treatments. Or they might study how it works if people take it at different times.
- They might study it in different people than earlier clinical trials did. For example, they might study how well it works for children or older adults. Doctors can also study how well a drug or treatment works over time.
- Drug makers may do phase IV clinical trials even if the FDA does not ask them to. They might do this to get FDA approval to use the drug in a new way. For example, they might want to use it for another type of cancer.
- Phase IV clinical trials can also check the safety of drugs or treatments being used now. They do this to make sure drug makers report any new or serious side effects. The FDA may take away a drug's approval if new research shows it is not as safe or effective as

earlier testing showed. Doctors cannot prescribe it any longer if this happens

Do I need to be in all the phases of a clinical trial?

No. You can join any phase of a clinical trial if you qualify to join. For example, you may join a phase II clinical trial whether you were in phase I, or not.

Sometimes different phases are done at the same time. If so, the research staff will let you know. You always have a choice to be in the clinical trial, and you may leave at any time.[9]

IV. CONCLUSION

Clinical Research and Clinical trials provide an essential link between scientific **discovery** and clinical practice. These trials are crucial to the translation of new knowledge into tangible benefits for patients, and the knowledge gained in a clinical trial can also inform and guide further research into the biology of the disease**.** After preclinical development, investigational new drug passes through clinical phases I, II, III and IV. These phases provide in detail explanation of pharmacokinetic, pharmacodynamic profile and side effect which may be harmful or beneficial, adverse effect and post marketing surveillance.

REFERENCES

[1] Information about clinical trial. Available from : URL http://www.temple.edu/pascope/about_trials.html
[2] Clinical trial wikipedia, the free encyclopedia. Jan 28 2008. Available from: URL http://en.wikipedia.org/ wiki/clinical_trial. 28 Jan 2008.
[3] Kulkarni S. K., Hand Book of Experimental Pharmacology, 3rd ed, VallabhPrakashan New Delhi, 2004, 21.
[4] Itkar S., Pharmaceutical Management, 3rd ed, NiraliPrakashan, Pune, 2007, 13.4-13.5.
[5] ICH Harmonised Tripartite Guideline for Good Clinical Practice 'Academy For Clinical Excellenge'.
[6] Pharmacist Career Profile: Clinical Research / Investigational Drug, Available From: URL: http://en.wikipedia.org/wiki/Randomized_controlled_t rial.
[7] Barar, F. S. K., Essential of Pharmacotherapeutics. 4 thed, S. Chand and Company Ltd; New Delhi, 2007, 57-59.
[8] Allen, L. V, Poporich, N. G, Ansel H. C., Pharmaceutical Dosage Forms and Drug Delivery System, 8th ed, B I Publications Pvt. Ltd.; New York, 2005, 45, 64-65.
[9] Satoskar, R. S., Bhandar, S. D., Ainapure, S. S., Pharmacology and Pharmacotherapeutic. 8th ed, Popular Prakashan, Mumbai, 2003, 64.