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CLINICAL TRIALS: A REVIEW

Ashwini V. Pawar *, Ajinkya P. Joshi, Harshal L. Tare.

TSPM's, Trimurti Institute of Pharmacy Jalgaon, Maharashtra, India

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For Correspondence:

Ashwini V. Pawar

TSPM's, Trimurti
Institute of Pharmacy
Jalgaon, Maharashtra,
India

ABSTRACT

This study shows that many global clinical trials organization have relocated their clinical trials research units to Indian , the Indian industry has become one of the most cost efficient in the world , it is growing fast and has emerged as a popular destination for global clinical trials although the clinical trials industry has been able to take advantage of financial gain from the global clinical trial activity .a clinical trials is a research study in human volunteers to answer specific health question carefully conducted clinical trials are fastest and safest way to improve health clinical trials effectiveness and constitute an important and highly specialized from of biological assay. . Capability- building for development of new drug is not occurring in a manner that can help the country tackle public health challenges. .

INTRODUCTION

The clinical trial defines as any experiment on human being for the assessment of effectiveness of new drug or combination of drug , new approaches of surgery or radiotherapy or technique to improve the diagnostic procedure of disease to improve the quality of life of patient. in clinical trial, new drug is administered to patient for estimation of pharmacokinetics, pharmacodynamics and safety profile purpose. A clinical trial is a research study that tests a new medical treatment or a new way of using an existing treatment to see if it will be a better way to prevent and screen for diagnose or treat a disease for any new drug to enter in clinical trial. it must pass preclinical studies involve in vitro studies and trials on animal population. Wide range of dosage of the study drug is given to animal subjected or to an in- vitro substrate in order to obtain preliminary efficacy toxicity and pharmacokinetic information.

TYPES OF CLINICAL TRIAL

- 1) Treatment trial
- 2) Prevention trial
- 3) Observation trial
- 4) Diagnostic and Screening trial

1. Treatment trial: It is also called as intervention trial and intention of treatment trial is investigate the effect of treatment or combination of treatment which are not yet approved. The research or pharmaceutical company develop new drug and believe that the new drug would be effective in treatment of diabetes but is not tested on human being .

2. Prevention trial: In this trial, the tests are performed to find the new way for the prevention of same medical condition. The prevention trial may also conduct to prevent the patient form reoccurring of specific medical condition .

3. Observation trial : In this trial, the study perform in large groups of people . in observation trial patient do not receive any kind of any treatment but the researcher may ask to provide the information regarding health issue or ask for blood sample to investigate the disease condition.

4. Diagnostic and screening trial: These trial are conducted by aiming to find new ways or technique to detect and diagnose the medical condition.

A Therapeutic trial : In Therapeutic trial ,the given treatment believe to produce therapeutic effect which is likely to beneficial to same way

A Non - therapeutic effect : In this trial, the treatment unlikely to produce direct beneficial effect but can provide knowledge or information which may contribute toward the development of new treatment or procedure in future or information .

Single – blind clinical trial : In single blind clinical trial, subject or participant does not know about which possible treatment he is receiving .

Double – blind clinical trial: In double blind clinical trial neither the subject nor investigator know which treatment is being administered.

Triple- blind clinical trial: In triple blind clinical trial , subject investigator and data analyzes do not know regarding the name of treatment being received . this is possibility of interpretation or data analyzer know the treatment so it is mostly used in clinical trial design.

PHASES OF CLINICAL TRIAL

- Phase:-1
- Phase:-2
- Phase:-3
- Phase:-4
- Phase:-5

Phase 0:-

Phase 0 studies involve limited human exposure and haveany therapeutic intention. Trials also expressed as studies and are designed with motive of development of promising drug as expected studies. the major application of phase 0 trial development is to shorten the drug development process by accelerating the identification of promising drug and reduce development time and cost.

Phases	Goal	Number of participant	Dose limit	Application
Preclinical	Testing for pharmacokinetics ,pharmacodynamics and safety evaluated in animal	Unrestricted involvement of animal	Unrestricted dose range	To determine pharmacokinetic, Pharmacodynamics and safety evaluated in animal
Phase 0	Testing of pharmacokinetics and pharmacodynamics effect of drug	Very small number of volunteers[10-15]	Sub-therapeutic dose level	Help in the decision regarding go versus no go for further clinical studies.
Phase1	Testing of drug on healthy volunteers for dose selection	20-100 volunteers	Performed at normal dose and ascending level	Determine whether drug is effective and safe. Determine maximum tolerated dose
Phase 2	Testing of drug on patient to evaluated efficacy and safety	100-300 patient	At therapeutic dose level	Determine the therapeutic and safety effect of drug
Phase3	Testing on drug on patient to evaluate efficacy and safety	300-1000 and more	At therapeutic dose level	Determine and therapeutic and safety effect of drug
Phase 4	Post marketing surveillance	Whole population anyone who are seeking for treatment	At therapeutic dose level	Determine the effect of drug for long term use and for adverse effect
Phase 5	Comparative research and community based research	none	No dosing	Research made on collected data

Phase 1:

Phase1 clinical trial has been conducted to collect the data regarding safety. The trial often performed in center and in close observation under full time medical staff .the phase 1 trial included small number[20-100] of volunteers for the study. In this trial, small number of administered single dose of drug and observer for pharmacokinetic and pharmacodynamics data

- **Phase 2:-**

Phase 1 and 2 are dose finding studies where the drug has tested for biological and therapeutic response in volunteers .the dose which is selected in this study determined as most successful dose [MSD] at which it shows therapeutic effect without any toxicity or adverse effect. The activity which are determined in phase. 1 trial of are administered to large number of in phase 2 trial in order to produce same therapeutic effect without showing any signs of toxicity. In some trials, the phase 2 trial designed to perform both efficacy and toxicity.

- **Phase 3:-**

Phase 3 clinical trial has been designed to analyze the therapeutic effect of new drug .the study has been conducted on large number of patient [300-3000 or more] in order to assess the therapeutic effect of drug by comparison with standard treatment . Phase 3 trial is most expensive due to longer duration and size. Phase 3 trial is difficult to design and run and it is time consuming study.

- **Phase 4:-**

Phase 4 trial also called as “ post marketing surveillance “ and it can be performed with the help of regulatory authority or by sponsoring group for finding new market of the drugs. After approval of FDA , the proven therapy make available for general population use. The main intention of the phase 4 trial is to check how the drug is work in real world .phase 4 trial has been designed to find out long term adverse effect of drug in large population of patient for longer duration of time are not conduct during phase 2 and 3 clinical trial .

- **Phase 5:-**

Phase 5 clinical trial also called as translation research which refers the community based research studies. phase 5 trial has been considered as field research and is designed to move from bench to bed side. Phase 5 trials are comparative effectiveness research and community based research. Research performed on the collected data to determine the impact of new drug therapy in wide spread clinical practice.

CLINICAL TRIALS FOR BREAST CANCER:-

- **Symptoms and diagnosis**

Breast cancer symptoms very widely - from lumps to swelling to skin change and many breast cancer have no obvious symptoms at all.

It's important to have anything unusual checked by your doctor,

- **SYMPTOMS**

1. Swelling of all or part of the breast
2. Skin irritation or dimpling
3. Breast pain
4. Nipple pain or the nipple turning inward
5. Redness or thickening of the nipple or breast skin
6. A nipple discharge other than breast milk
7. A lump in the underarm area

- **TYPES OF BREAST CANCER**

1. Ductal carcinoma in situ [DCIS]
2. Invasive ductal carcinoma [IDC]
3. IDC type: lobular carcinoma of the breast
4. IDC type : medullary carcinoma of the breast
5. Invasive lobular carcinoma [ILC]
6. Inflammatory breast cancer
7. Male breast cancer
8. Molecular subtypes of breast cancer

- **DIAGNOSIS**

1. Getting your pathology report
2. Cell grade
3. Rate of cell growth
4. Tumor necrosis
5. Size of the breast cancer
6. Surgical margins
7. HER2 status
8. Tumor genomic assays
9. Recurrent breast cancer

TREATMENT AND SIDE EFFECT

Instead of only one or two options, today there's an overwhelming menu of treatment choices that fight the complex mix of cells in each individual cancer

1. Planning your treatment :-

What types of treatment are available the most likely sequence of treatment, treatment option by cancer stage, and fitting treatment into your schedule.

2. Getting a second opinion:-

Reasons for getting a second opinion about your treatment plan , how to go about your treatment plan , how to go about getting one .and what to do once you've got it

3. Surgery:-

Breast – conserving surgery mastectomy, and lymph node dissection and what to expect from each

4. Chemotherapy :-

How chemotherapy works, who should get in different type and combination.

5. Radiation :-

How radiationtherapy works, who it's for advantages, side effect, and what to expect when you get it

6. Hormonal therapy :-

The link between hormones and breast cancer and how different group of drug – including ERDS, SERMS, and aromatase inhibitors.

7. Targeted for pain:-

Ways to treat cancer –and treatment – relatedpain, including types of medication and trips on talking to your doctors about pain.

8. Treatment therapy:-

Get them, how they're given, side effect, and major studies.

ROLE OF PHARMACISTS IN CLINICAL TRIA

Pharmacists have an active role to play in research and clinical trial first of all , we necessary required for proper storage of the investigation medicinal product IMPs either and recorded.

It is also the pharmacist duty to ensure there is constant supply of IMPs at all times ,and that they accordingly.

CONCLUSIONS:-

A clinical trial for any new drug follows under the guidelines of ICH and GCP, clinical trial are conducted.

The review conclude that the clinical trial industry in India has great potential to become the most favorable destination in the world because of low skilled professionals ,and , the

availability of a large and diverse patient pool , many global CROs relocate their research units to for Drug , development activities .

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