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Clinical Trials - A Mini Review

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Review Article

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ABSTRACT

These are the trials which are conducted on human being to check the efficacy and Action of the drug whether it shows proper action on the pre-determined site of the body or not. These trials are very useful and show accurate results. The purpose of clinical trials is research, so the studies follow strict scientific standards. These standards protect patients and help produce reliable study results. Clinical trials are usually done first on animals and then on human beings.

INTRODUCTION

Clinical trials are usually conducted on people with various tests and treatment
Risks and causes – how genetics, lifestyle and other factors can increase people's risk of cancer
Preventing cancer – using drugs, vitamins or diet to reduce risk
Screening – for people at higher than average risk, or for the general population
Diagnosing cancer: new tests or scans ⁽¹⁻²⁰⁾
Treatments – new drugs or combinations, new types and methods of giving treatment
Controlling symptoms or side effects – new drugs or complementary therapies

Description

Clinical trials are of two types
Preclinical trials usually take place before testing on humans
Clinical trials involve people tests and treatments

Under preclinical trials there are several stages:
Drug target, bio assay, drug dose, FDA approval (**Figure 1**)

Drug target: Usually different drugs will show action on different parts of the body. It may be cellular or topical. This targeting of drug is specifically meant for knowing the action of drug. In this phase we can also know whether the used drug shows its effect on the particular site or not. ⁽²¹⁻³⁰⁾

Bio assay: It is the process in which a tissue or cell is used to determine the pharmacological action of a drug. This stage also includes screening of bio assay which means whether the drug is safe or not. And also the efficiency of the drug before it is done on humans.

Drug dose: Every drug has its own toxic level. If a drug exceeds the required amount of dose while using in clinical trials it shows adverse effects. In this stage the dose of drug will be fixed.

FDA approval: In this step drug will be sent to FDA. Here they will check the manufacturing, purity, and all physical parameters and will be tested for safety.

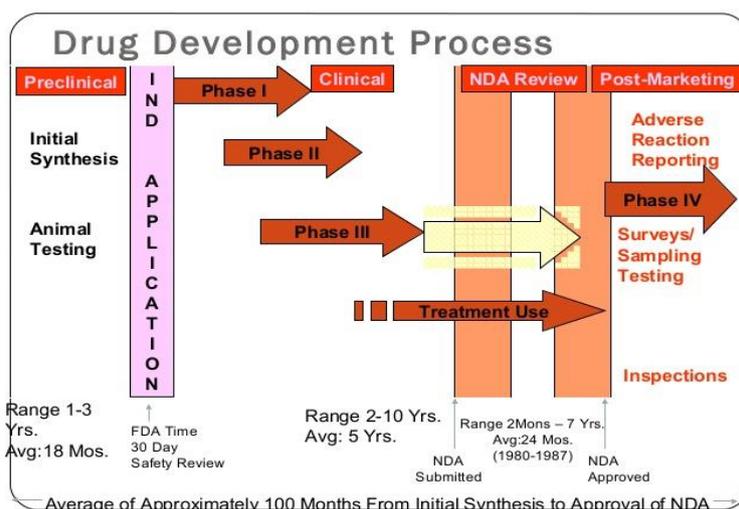


Figure 1. Phases of clinical trials

Clinical trials

Phase zero:

They aim to learn how a drug is processed in the body and how it affects the body.

In these trials, a very small dose of a drug is given to about 10 to 15 people.

Disadvantages:

All drugs cannot show results with in short dose or short span of time

Because pharmacokinetic properties differ from drug to drug

Cost of drug may also differ. (31-50)

Phase 1:

This phase is to determine the tolerated dose of the drug

And drug toxicity levels are also checked.

Based on the drug category single dose or multiple dose is given.

Single dose is to understand the adverse effects and toxicity of the drug.

Multi dose is to understand the pharmacokinetics and dynamics of the drug

Healthy individuals are usually taken for the phase 1 trial.

Phase 2:

Phase 2 trials will be conducted from months to years.

This includes efficacy and safety of patients. (Figure 2)

Duration of therapy, route of administration (51-60)

Phase 2 trails can be done with single drug or placebo drug

In singled drug trails no of patients will be less (10-20)

In placebo drug trails no of patients will be more (50-500).

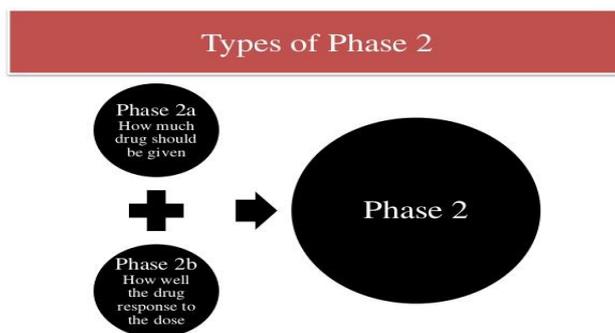


Figure 2. Different trials in phase 2

Phase 3:

Phase 3 trials will be done up to 6-10 years
It mainly deals with toxicity, productivity, and carcinogenetic factors of the drug.
Phase 3 trails are of two types (61-80)
Phase 3A: this is mainly focused on new drug which is used
Phase 3B: concentrates mainly on diseases beyond the original use.
In phase 3 trails new drug should be filed for new drug application.
Drug should be accepted by drug controller general of India.
Then it should be reviewed by DCGI
Now the drug can be released in to market

Phase 4:

This phase is also known as post market surveillance (Figure 3)
In this phase evaluation of drug dose, duration of treatment are decided
Risk and quality assessment are done here It is experiment which is designed to study the efficacy and safety of drug.

New drug clinical trials



Figure 3. flow chart of clinical trials

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