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What is Clinical Drug Trials and what are the four phases of clinical trials

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Abstract

A clinical study involves exploration using mortal levies(also called actors) that's intended to add to medical knowledge. There are two main types of clinical studies clinical trials(also called interventional studies) and experimental studies.ClinicalTrials.gov includes both interventional and experimental studies.

Introduction

In a clinical trial, actors admit specific interventions according to the exploration plan or protocol created by the investigators. These interventions may be medical products, similar as medicines or bias; procedures; or changes to actors' geste , similar as diet [1]. Clinical trials may compare a new medical approach to a standard bone that's formerly available, to a placebo that contains no active constituents, or to no intervention. Some clinical trials compare interventions that are formerly available to each other. When a new product or approach is being studied, it isn't generally known whether it'll be helpful, dangerous, or no different than available druthers (including no intervention). The investigators try to determine the safety and efficacity of the intervention by measuring certain issues in the actors. For illustration, investigators may give a medicine or treatment to actors who have high blood pressure to see whether their blood pressure decreases [2,3].

In general, clinical studies are designed to add to medical knowledge related to the treatment, opinion, and forestallment of conditions or conditions. Some common reasons for conducting clinical studies include

• assessing one or further interventions(for illustration, medicines, medical bias, approaches to surgery or radiation remedy) for treating a complaint, pattern, or condition [4].

• Chancing ways to help the original development or rush of a complaint or condition. These can include drugs, vaccines, or life changes, among other approaches.

• assessing one or further interventions aimed at relating or diagnosing a particular complaint or condition

• Examining styles for relating a condition or the threat factors for that condition

• Exploring and measuring ways to ameliorate the comfort and quality of life through probative care for people with a habitual illness [5].

Clinical exploration is medical exploration involving people. There are two types, experimental studies and clinical trials.

experimental studies:

Observe people in normal settings. Experimenters gather information, group levies according to broad characteristics, and compare changes over time. For illustration, experimenters may collect data through medical examinations, tests, or questionnaires about a group of aged grown-ups over time to learn further about the goods of different cultures on cognitive health. These studies may help identify new possibilities for clinical trials [6].

Clinical trials:

Clinical trials are exploration studies performed in people that are aimed at assessing a medical, surgical, or behavioral intervention. They're the primary way that experimenters find out if a new treatment, like a new medicine or diet or medical device(for illustration, a trendsetter) is safe and effective in people. frequently a clinical trial is used to learn if a new treatment is more effective and/ or has lower dangerous side goods than the standard treatment [7].

Other clinical trials test ways to find a complaint beforehand, occasionally before there are symptoms. Still others test ways to help a health problem. A clinical trial may also look at how to make life better for people living with a life- hanging complaint or a habitual health problem [8].

four phases of clinical trials:

Clinical trials advance through four phases to test a treatment, find the applicable lozenge, and look for sideeffects.However, after the first three phases, experimenters find a medicine or other intervention to be safe and effective, If.

Clinical trials of medicines are generally described grounded on their phase. The FDA generally requires Phase I, II, and III trials to be conducted to determine if the medicine can be approved for use [9].

• A Phase I trial tests an experimental treatment on a small group of frequently healthy people(20 to 80) to judge its safety and side goods and to find the correct medicine lozenge.

• A Phase II trial uses further people(100 to 300). While the emphasis in Phase I is on safety, the emphasis in Phase II is on effectiveness. This phase aims to gain primary data on whether the medicine works in people who have a certain complaint or condition. These trials also continue to study safety, including short- term side goods. This phase can last several times [10].

• A Phase III trial gathers further information about safety and

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effectiveness, studying different populations and different tablets, using the medicine in combination with other medicines. The number of subjects generally ranges from several hundred to about,000people. However, it'll authorize the experimental medicine or device, If the FDA agrees that the trial results are positive.

• A Phase IV trial for medicines or bias takes place after the FDA approves their use. A device or medicine's effectiveness and safety are covered in large, different populations. occasionally, the side goods of a medicine may not come clear until further people have taken it over a longer period of time [11].

Discussion

In a clinical trial, participants receive specific interventions according to the research plan or protocol created by the investigators. These interventions may be medical products, such as drugs or devices; procedures; or changes to participants' behavior, such as diet [12]. Clinical trials may compare a new medical approach to a standard one that is already available, to a placebo that contains no active ingredients, or to no intervention. Some clinical trials compare interventions that are already available to each other. When a new product or approach is being studied, it is not usually known whether it will be helpful, harmful, or no different than available alternatives (including no intervention). The investigators try to determine the safety and efficacy of the intervention by measuring certain outcomes in the participants. For example, investigators may give a drug or treatment to participants who have high blood pressure to see whether their blood pressure decreases [13,14].

In an observational study, investigators assess health outcomes in groups of participants according to a research plan or protocol. Participants may receive interventions (which can include medical products such as drugs or devices) or procedures as part of their routine medical care, but participants are not assigned to specific interventions by the investigator (as in a clinical trial). For example, investigators may observe a group of older adults to learn more about the effects of different lifestyles on cardiac health [15].

Drugs approved by the FDA are often watched over a long period of time in phase IV studies. Even after testing a new medicine on thousands of people, all the effects of the treatment may not be known. Some questions may still need to be answered. For example, a drug may get FDA approval because it was shown to reduce the risk of cancer coming back after treatment [16,17]. But does this mean that those who get it are more likely to live longer? Are there rare side effects that haven't been seen yet, or side effects that only show up after a person has taken the drug for a long time? These types of questions may take many more years to answer, and are often addressed in phase IV clinical trials [18].

- Phase IV studies look at drugs that have already been approved by the FDA. The drugs are available for doctors to prescribe for patients, but phase IV studies might still be needed to answer important questions [19].
- These studies may involve thousands of people.
- This is often the safest type of clinical trial because the treatment has already been studied a lot and has likely been given to many people. Phase IV studies look at safety over time.
- These studies may also look at other aspects of the treatment, such as quality of life or cost effectiveness.

Conclusion

You can get the drugs used in a phase IV trial without being in a study. And the care you would get in a phase IV study is very much like the care you could expect if you were to get the treatment outside of a trial. But in phase IV studies you're helping researchers learn more about the treatment and doing a service to future patients [20].

A group of 25 to 100 patients with the same type of cancer get the new treatment in a phase II study. They're treated using the dose and method found to be the safest and most effective in phase I studies.

Usually in a phase II clinical trials, everyone gets the same dose. But some phase II studies randomly assign people to different treatment groups. These groups may get different doses or get the treatment in different ways to see which provides the best balance of safety and response.

Placebos (inactive treatments) are not used in phase II trials.

Phase II studies may be done at major cancer centers, community hospitals or even doctors' offices.

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Conflict of Interest

None

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