Commentary

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Drug Development: Phases in Clinical Trials

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Commentary

Clinical trials testing new treatments are divided into different stages, called phases. The earliest phase trials may inspect whether a drug is safe or the side effects it causes. Later phase trials aim to check whether a new treatment is better than existing treatments. There are 3 main phases of clinical trials – phases 1 to three. Phase 1 trials are the earliest phase trials and phase 3 is later phase trials. Some trials have an earlier stage called phase 0, and there are some phase 4 trials done after a drug has been licensed. Some trials are randomized. This suggests the people participating are put into one amongst the treatment groups randomly. Doing this implies the results are more reliable.

Phase 0 trials

Phase 1 trials are usually the earliest trials of medication in people. But your doctor might ask if you'd wish to join a phase 0 study. These studies aim to search out if a drug behaves within the way researchers expect it to from their laboratory studies. Phase 0 studies usually only involve a little number of individuals and that they only have a very small dose of a drug. The dose of the drug is just too small to treat your cancer, but you're also less likely to possess side effects.

Phase 0 trials aim to search out things such as: Whether the drug reaches the cancer cells, what happens to the drug within the body, you may have extra scans and provides extra samples of blood and cancer tissue (biopsies) to assist the researchers compute what's happening.

Phase 1 trial

Phase 1 is usually written as phase I clinical trial. They're usually small trials, recruiting only a couple of patients. The trial could also be hospitable people with any sort of advanced cancer, usually people who have already had all other available treatments.

Phase 1 trials aim to seek out: what quantity of the drug is safe to provide, what the side effects are, how the body gets rid of the drug. Patients are recruited very slowly onto phase 1 trials. So albeit they do not recruit many of us, they will take an extended time to finish. They are often dose escalation studies. This suggests that the primary few patients that participate (called a cohort or group) are given a really small dose of the drug. If all goes well, subsequent group features a slightly higher dose. The dose is gradually increased with each group. The researchers monitor the side effects people have and the way they feel, until they find the simplest dose. During a phase 1 trial you'll have many blood tests because the researchers check out how your body copes with and gets obviate the drug. They carefully record any side affects you will have and after you have them. The main aim of phase 1 trials is to seek out about doses and side effects. They have to try to this first, before testing the potential new treatment to examine if it works. Some people participating may have the benefit of the new treatment, but many won't.

Phase 2 trials

Phase 2 is usually written as phase II clinical trial. Not all treatments tested during a phase 1 trial make it to a phase 2 trial. These trials are often for people that all have an equivalent sort of cancer, or for people that have differing types of cancer.

Phase 2 trials aim to seek out: If the new treatment works tolerably to be tested during a larger phase 3 trial, which sorts of cancer the treatment works for, more about side effects and the way to manage them and usage.

These treatments are tested in phase 1 trials, but you'll still have side effects that the doctors do not know about. Treatments can affect people in several ways. Phase 2 trials are usually larger than phase 1. There could also be up to 100 approximately people participating. Sometimes during a phase 2 trial, a replacement treatment is compared with another treatment already in use, or with a dummy drug (placebo). Some phase 2 trials are randomized. This suggests the researchers put the people participating into treatment groups randomly. Determine about randomized trials.

Phase 3 trials

Phase 3 is usually written as phase III clinical trial. These trials compare new treatments with the simplest currently available treatment (the standard treatment).

Phase 3 trials aim to seek out: Which treatment works better for a specific sort of cancer, more about the side effects, how the treatment affects people's quality of life. They may compare standard treatment with: a totally new treatment or different doses of an equivalent treatment or having an equivalent treatment more, or less, often or a replacement way of giving a regular treatment (radiotherapy for example). Phase 3 trials usually involve more patients than phase 1 or 2. This is often because differences in success rates could also be small. So, the trial needs many patients to be ready to show the difference. Sometimes phase 3 trials involve thousands of individuals in many various hospitals and even different countries. Most phase 3 trials are randomized. This suggests the people participating are put into treatment groups randomly. See our information about randomized trials.

Phase 4 trials

Phase 4 is usually written as phase IV clinical trials. These trials are done after a drug has been shown to figure and has been licensed.

Phase 4 trials aim to seek out : More about the side effects and safety of the drug, What the future risks and benefits are, How well the drug works when it's used more widely, having information about how drugs are licensed

Trials covering quite one phase

Most trials are only one phase. But some trials cover quite one phase. For instance, an equivalent trial can include both phase 1 and phase 2 are written as phase 1/2 phase 2/3.