Lung Fibrosis Clinical Trials

Why consider taking part in a clinical trial?

Clinical trials are a vital element in the development of new treatments. A clinical trial is a research study that tests the effect of a treatment, referred to as an Investigational Medicinal Product (IMP). It's important to let your physician know if you are interested in participating in trials as they can suggest suitable studies. It's important to note also that not all people are eligible for all trials. In a trial participants are closely monitored, and the information is used to understand whether the IMP is safe and effective. Clinical trial participants are volunteers. Clinical trials are approved and monitored by independent ethics committees and government medicines regulators before they start and during the trial to ensure participants' rights are protected and to make the trials as safe as possible.

Pros	Cons
• Early access to new treatments • Frequent monitoring by the research team • May help other people in the future • Opportunity to contribute to research and scientific knowledge • May help family members in inherited conditions	• May be given placebo (inactive IMP) • Frequent clinic / hospital visits • Extra assessments, such as blood tests • Negative effects of IMPs may not be fully known at the time of the trial

Clinical Trial Phases and Types

Clinical trials are conducted in a series of steps called "phases." Each phase has a different purpose and helps researchers answer different questions.

Phase I trials: Researchers test an IMP in a small group of healthy –participants- for the first time to learn how the body handles it and identify possible safety issues and side effects.

Phase II trials: The IMP is given to a larger group of people diagnosed with a medical condition to determine if it may be effective in treating the condition and to further study its safety.

Phase III trials: The IMP is given to large groups of participants with the medical condition to confirm its effectiveness, monitor side effects, compare it with standard or similar treatments, and collect information that will allow the IMP to be used as safely as possible.

Phase IV trials: After an IMP is approved as a treatment and made available to the public, researchers track its safety profile in a broad population of people with the medical condition, seeking more information about benefits, optimal use and side-effects.

Randomised Control Trials: Participants are randomly allocated to IMP or the other (like flipping a coin). Some trials involve a 'placebo' where those randomised to the placebo group receive something that looks identical to the IMP but has no active ingredient. These features are an important part of a trial as they help make sure that the results are true and accurate.

Standard of Care: It is important to note that some trials are done in addition to "Standard of Care". This means that clinical trial participants can enter a study if they are already receiving the best available treatment ('Standard of Care"). This will continue throughout the trial.

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What does taking part in a clinical trial involve?

Each clinical trial has different requirements, but there are some common features. Participants are given a 'participant information and consent form' which provides an outline of the purpose of the study, what to expect and potential benefits and risks. This information should be read carefully and discussed with the participant's family and medical team. The consent form must be signed by the participant and dated, providing written informed consent to participate before starting the trial.

After providing consent, but before starting any trial, the researchers will assess the participant's eligibility based on stage of disease, age, medical conditions or other factors.

Detailed health and wellbeing assessments will be made before starting the IMP and at regular intervals during and after the trial. Participants may need to attend a hospital for these assessments.

The researchers will keep in touch with participants during the trial to monitor wellbeing and check for any side effects. Participants should also maintain contact with other members of their healthcare team while on the trial.

During the trial, participants should inform the researchers of any changes to their health or medications, attending the assessments and filling out the trial forms as requested.

NOTE: Taking part in any clinical trial is voluntary, which means participants are free to withdraw at any time, without ongoing treatment being affected.

Clinical Trial Questions to Ask

- How long will the trial be?
- Is the IMP already marketed as a medicine?
- Is the IMP being compared with another active treatment or with placebo?
- What is the chance (probability) that participants will receive the IMP versus an inactive placebo?
- Will participants (or their healthcare team) know what treatment they're on?
- How often will participants need to go to the hospital? Are costs (travel, parking) reimbursed?
- What are potential benefits and side effects?
- Are there treatments for known side-effects?
- Will participants have to stop current treatments?
- What happens when the trial concludes?
- What happens if a participant stops the trial early?
- Can participants receive the IMP after the end of the trial if they want to?
- When will the results be available and can participants see the results?
- Are there any additional tests needed and do those tests have side effects
- What do participants do if they have a medical problem during the trial?

Find trials recruiting in Ireland by visiting www.clinicaltrials.gov or ask your physician.

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