Access to promising treatments: Clinical trials 101

By Asfandyar Mufti and Dr. Isabelle Boileau

All skin patients hope for a cure or better treatment in their lifetime. Clinical trials play a large role in making these wishes come true.

What is a clinical trial?

Clinical trials are research studies that have been designed to test promising new therapies, devices, drugs or drug combinations in people, with the hope of treating and preventing human diseases and improving quality of life.

Who should participate?

Individuals who choose to participate in a clinical trial are either healthy or patient volunteers. Patients may want to consider a clinical trial if they have little or no medical coverage, have tried currently available treatments without relief or wish to explore novel therapeutic options.

What to expect from participating in a clinical trial

Clinical trials can vary significantly depending on the type of drug or therapy being tested. Consequently, patients will have different experiences from study to study. In general, a clinical trial will include a series of consultations such as an initial visit and a screening interview to assess you as a suitable candidate.

During these initial meetings, patients are usually asked to provide blood and urine samples, share their complete medical history and undergo a medication check. In addition, telephone calls and follow-up meetings will take place for the duration of the trial. Some studies last only a few weeks, while others can go on for years.

Patients are sometimes asked to stop all current treatments for the condition being tested before beginning a trial; it is therefore possible that their disease worsen during this time.

Questions to think about

Questions you may want to ask before agreeing to take part in a trial include the following:

- What are the risks and benefits of this study?
- How much time will my participation take?
- Will I receive a placebo?
- How will this trial affect my current condition?
- Will I be able to access the new treatment once the trial is over?

These questions should be asked during the initial conversation with the researchers conducting the study.

In order to participate in a clinical trial you must provide informed consent, meaning: (1) you have an adequate understanding of the information; (2) you are making an autonomous decision; (3) you understand the potential consequences. Consenting in trial is voluntary and can be withdrawn at any time. The study team will ensure that appropriate care is given after withdrawing from a clinical trial.

After the trial

At your last visit, all therapies will be collected and you will not receive any more medication. To continue your care, the study coordinator will usually schedule you a visit with your physician. If the trial was successful then your participation might provide access to the new treatment.

To search for clinical trials available in your area, visit **www.clinicaltrials.gov** or speak with your dermatologist. CS

5 Things you should know about clinical trials

- ✔ They offer access to promising new treatments.
- ✔ The new treatment may have fewer side effects than current treatments.
- ✔ Candidates are contributing to science and helping others.
- ✘ In a randomized clinical study, participants may not be able to choose whether they receive the treatment or a placebo.
- ✘ The treatment may have negative side effects or not work. In these cases, patients are sometimes removed from the trial.

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