



Clinical Trials

At any given time, dozens of clinical trials conducted by licensed health care professionals are underway. These trials, lasting from a few weeks to many years, determine just how safe and effective new treatments may be. Participating in a clinical trial is completely voluntary, but it isn't for everyone.

Fast facts

- Clinical trials test promising treatments or new ways to use existing therapies.
- Before participating in a clinical trial, patients should understand the potential risks and benefits.
- To find about clinic trials and whether they are right for you, talk with your rheumatologist.

What is a clinical trial?

Doctors use a variety of different medications to treat patients who have arthritis and other rheumatic diseases. Before any of these medicines can be prescribed, the federal Food and Drug Administration (FDA) has required strict testing to be sure they are safe and effective at treating a particular disease. Most of this testing and evaluation process is done through clinical trials.

A clinical trial is a research study performed by physicians and other health professionals in which new treatments are tested on volunteers. Safety is always at issue. These studies take place only after laboratory investigations indicate that the new treatment has some potential to be effective and that it seems to be relatively safe. Then, prior to conducting the study on volunteers, an institutional review board (IRB) must approve the safety of each proposed study. The IRB also oversees the study to ensure that all federal regulations that protect human volunteers are being followed.

While participating in such a study, patients with a particular condition (such as [rheumatoid arthritis](#)) are given a new medicine and then followed very closely. During follow-up, study personnel again evaluate the safety of the new medicine as well as how well it helps control symptoms.



Many studies are ‘blinded’ to ensure accurate measurement. This means patients taking the study medication may be compared to patients taking another medication or a placebo (an inactive agent, like a sugar pill). Neither the study personnel nor the patients know for sure which treatment is being given.

What information will be provided?

Doctors regularly provide information about possible risks and benefits of treatments during office visits. However, the information for a clinical trial is much more detailed. In particular, the list of possible side effects for a medicine being tested will often be much longer than for an already FDA approved medicine. (Remember, all the risks of the new medication may not yet be known.) This does not mean that the medication under investigation is necessarily more dangerous. Instead, this type of detailed disclosure of all possible risks, possible improvements in symptoms, and alternative treatments available ensures patients are fully informed before enrolling in the study. After discussing any questions with the study staff, patients who are willing to participate sign “informed consent.”

Is participation voluntary?

Participation in any research study is entirely voluntary. Only patients who have read all of the information and decide to participate on their own are enrolled in clinical trials. Even after enrolling, patients can leave the clinical trial at any time and for any reason. Leaving the study will not affect their normal medical care in any way.

What are the benefits and risks of participation?

Benefits of participating in a clinical trial include:

- Access to new and, potentially, more effective medicines before they become available to the general public.
- Free treatment for many clinical trials, including the medicine being evaluated, doctor visits, physical examinations, laboratory tests, and other tests.
- The opportunity to help advance medical knowledge and enable doctors to expand treatments for particular conditions, including arthritis.

Possible risks of participation include:

- Some patients may receive placebos (inactive ingredients sometimes referred to as “sugar pills”) during the study. This means every participant will not receive active medication which could lead to a worsening condition.
- Participants may experience side effects from the study medication. While any medicine can cause side effects, doctors generally know much less about medicines still under investigation.

It is important to remember that patients can leave a study at any time, for any reason. These include intolerable side effects, or if their condition worsens or is not improving. Moreover, many studies in rheumatology include some provision for providing treatment to patients if their condition does not improve, even before the study ends.



A final point to consider—which may be an advantage or disadvantage depending upon the patient—is that clinical trials need more monitoring than standard clinical practice. This means visits to the doctor tend to be longer and more frequent than regular clinic visits.

How do I know if a clinical trial is right for me?

Clinical trials are limited not only to a particular condition, such as [rheumatoid arthritis](#) (RA), but also to people who meet carefully defined criteria. For example, some trials are for RA patients who are taking the medication [methotrexate](#) (*Rheumatrex*), whereas other trials may exclude patients taking this medication. To accurately assess whether a new medication is effective in helping arthritis, many studies enroll only patients who have a certain level of disease activity (e.g., counting the number of joints affected, looking at lab test results, and asking specific questions). Clinical trials may also exclude patients with other illnesses that might adversely affect health and interfere with an accurate assessment of the study medicine's safety.

How can I find out about clinical trials?

The best way to find out about clinical trials in rheumatology is to ask your rheumatologist, who can answer your questions and refer you to appropriate trials. Information about clinical trials can also be found on reliable websites, such as www.clinicaltrials.gov.

Points to Remember

- The safety and effectiveness of new treatments are determined by clinical trials.
- Participation in a clinical trial is entirely voluntary, and depends on an understanding of the possible benefits and risks associated with participating in a particular trial.

The role of a rheumatologist

Rheumatologists are specialists in the diagnosis and care of patients with various musculoskeletal disorders. A number of rheumatologists also serve as investigators for clinical trials, especially for newer treatments. Even those who do not actively participate in clinical trials are familiar with many of the potential risks and benefits of participating in trials. You may always talk to your doctor if you have any questions about clinical research.

To find a rheumatologist

For more information about rheumatologists, [click here](#).

For a listing of rheumatologists in your area, [click here](#).

For more information

The American College of Rheumatology has compiled a list of [clinical trial sites](#) to give you a starting point for your own additional research. The ACR does not endorse or maintain these websites, and is not responsible for any information or claims provided on them. It is always best to talk with your rheumatologist for more information and before making any decisions about your care.

The Arthritis Foundation

www.arthritis.org



National Institute of Arthritis and Musculoskeletal and Skin Diseases Information Clearinghouse

www.niams.nih.gov

Federally maintained registry of clinical trials

www.clinicaltrials.gov

Reviewed February 2012

Written by Arthur Kavanaugh and reviewed by the American College of Rheumatology Communications and Marketing Committee.

This patient fact sheet is provided for general education only. Individuals should consult a qualified health care provider for professional medical advice, diagnosis and treatment of a medical or health condition.

© 2012 American College of Rheumatology