Resource

What is Clinical Research?

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Print

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The term “medical research” encompasses a broad range of activities within the clinical world, all aimed at improving or maintaining human health.

There are many different ways that research can be carried out within medicine. Research can vary from a simple questionnaire study, audits, and additional blood tests in clinic to clinical trials. Carrying out research is essential to find out whether one treatment is safer and more effective than another, although not all clinical trials aim to test new drugs. In some case, however, new and potentially valuable drugs need to be tested, and health professionals aim to provide the highest standard of care to those who participate in research.

What are Clinical Trials?

Clinical trials are research studies that involve patients. Clinical trials are a vital step in the process of transferring scientific concept into medical reality. Often these studies are in conjunction with a pharmaceutical company. Clinical trials are carried out for various different reasons:

- To test a new drug treatment for a specific disease.
- To assess the effectiveness of a drug currently on the market.
- To compare the effectiveness between different drugs.
- To determine other factors that may influence the action of the drug.
- New therapies are never put into practice until proven safe and effective.

Clinical Trials in Rheumatoid Arthritis.

There are many clinical trials that take place into rheumatoid arthritis (RA), and the importance of such studies can be seen in the new treatments that have become available in the last ten years for RA with drugs such as the anti-Tumour Necrosis Factor-alpha (anti-TNFa) treatments.

What sorts of assessments are carried out on patients during research trials in RA.?
We have outlined some of the assessments that are carried out during clinical trials into RA. This list may vary from trial to trial. The aim of this list is to give you some idea of what you could expect.

Patient Assessments

- Blood tests to measure inflammation. For example, ESR and CRP. These tests are carried out regularly to assess disease activity
- Questionnaires e.g. Health Assessment Questionnaire (HAQ)
- Examinations of joints for swelling and discomfort
- Examination of knuckle joints by ultrasound

Who will look after me if I take part in a trial?

You will see a number of people who make up the research team.
A research team is made up of doctors and nurses who specialise in research. They all have a special interest in Rheumatology and also the special area of research that is being studied. They also have good clinical experience of rheumatology. Very often, they will be doing research in addition to their clinical work. At all times during studies, the researchers work very closely with your rheumatologist and specialist nurses and GP's, to keep them informed of what is going on.

A rheumatology research sister is a qualified nurse with a specialist interest in rheumatology. They will have had previous experience working in a clinical rheumatology setting, usually in an acute hospital setting or outpatient department. They have moved into the field of research as they are committed to helping to find new ways of treating their patients with all types of arthritis. They work closely with rheumatology specialist nurses and doctors, and as a result, you will usually come into contact with them during your outpatient visits. Their main focus of work is to ensure you receive the right level of care. You can discuss any anxieties and concerns you might have with them.

Why are clinical trials important?

Trials are essential to find out whether one treatment is safer and more effective than another. New and potentially valuable drugs need to be tested by health professionals who will ensure that the study considers safety and well-being as the top priority and will provide the highest standard of clinical care for their patients.

Informed Consent

This is of the utmost importance to you if you consider taking part in a clinical trial. This will ensure that the trial and potential side effects have been explained to you in full. Before making the decision to join a trial, you should feel confident that you have been given all the information you need. The researchers will explain the trial to you and give you written information to take away with you. You will be given time to think it over and talk about it with your friends, family or GP. It's entirely up to you whether you take part – you are never under any obligation.

It is also important to know that even if you choose to enter a study, you are free to withdraw at any time, for any reason.

Ethics:

All clinical trials that take place in the UK must be approved by an independent ethics committee. All aspects of the study and potential study population are reviewed. The study must be approved by the committee before the study proceeds. The purpose of the ethics committees is to ensure that clinical trials are safe, worthwhile and protect the interests of the study population. They must also be registered by the European Clinical Trials Database (EudraCT).

How are Clinical Trials Regulated?

"The Medicines for Human Use (Clinical Trials) Regulations 2004" came into effect in May 2004. These Regulations
"..Help to ensure that the rights, safety and well-being of clinical trial subjects are protected by requiring sponsors of trials to be responsible for designing, conducting, recording and reporting clinical trials according to internationally recognised principles of Good Clinical Practice (GCP)." Clinical Trials are regulated by the European Clinical Trials Directive (Eu-CTD.) Medicines that are used in clinical trials are rigorously governed by the MHRA (Medicines and Healthcare Regulatory Authority.) All researchers have strict guidelines to adhere to in order to comply with these regulations and are monitored during and after the trial period

Where can I find out more information?

www.rheumatology.org.uk – This is the website for the British Society of Rheumatology, which has links to recent research publications related to rheumatoid arthritis.

Read more

Treatment Updates

From new drug treatments being approved or starting drug trials to an improved understanding of the drugs already existing as treatments in RA and the optimal ways of using these drugs to

treat the condition, our drug updates will help to inform patients of the latest information on RA drugs.