NHS
Wrightington, Wigan and Leigh Teaching Hospitals
NHS Foundation Trust

INTRANET - Oncology Research

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CC 037 Oncology Research - intranet only

Patient Information

Oncology

Why have I been given this leaflet?

Here at Wrightington, Wigan and Leigh Teaching Hospitals NHS Foundation Trust (WWL), we participate in various clinical research studies, looking into the causes of and treatment for cancer. These studies are carried out in many different disease groups and are all looking into ways of increasing our knowledge of how best to treat the disease and the symptoms associated with it. Also, many studies are looking into the causes of the disease, which will hopefully benefit future generations.

All trials have guidelines about who can take part; this means that there may not always be an appropriate clinical trial for you to participate in. For example, pregnant women may not be able to participate in certain studies due to the type of medication involved.

However, if there is a study that is suitable for you whilst you are being treated at this Trust, you may be approached by a member of the Oncology Research Team or one of the Medical / Surgical Teams involved with your care. You would then be provided with a study specific patient information sheet, fully detailing the study. Before deciding whether to take part in the study, please read the information sheet fully and discuss it further with other people if you wish, for example family members or your General Practitioner (GP).

For now, it is most important that you understand what a clinical trial is and what it involves.

What is a clinical trial?

Clinical trials are medical research studies which test whether different treatments are safe and how well they work. Some trials involve healthy members of the public, and others involve patients who may be offered the option of taking part in a trial during their care and treatment.

Clinical trials have many aims, including:

- To prevent disease and reduce the number of people who become unwell
- Treat illness
- Improve survival rates
- Improve quality of life
- Diagnose disease and health problems

We need evidence from trials to know which treatments work best.

Many treatments that are now widely received by patients were initially tested in clinical trials.

Trial design and approval

Clinical trials are designed by doctors and other specialists, with input from a wide range of people, including patients.

Statisticians (experts who study data) work together with various people including doctors, nurses, patients, trial managers and researchers to design the best possible trial. Once the trial has been designed it is sent to a Research Ethics Committee, which is an independent group of people. The Ethics Committee makes decisions on important issues such as whether:

- The information provided to help people decide whether they want to take part in a trial is clear and satisfactory
- The way people will be asked to take part in a trial is appropriate
- The potential benefits are likely to outweigh any side effects

Different types of trial

Some examples of the different trials are:

Genetic studies – These try to understand why some people seem to be more susceptible to the disease. They usually involve a questionnaire and blood samples. There is no treatment in this type of study.

Drug trials – These trials aim to improve the treatment options for cancer. They sometimes involve a new drug, or a drug that is already an established treatment but is being trialled in a new setting or at a new dose. Some studies also compare drugs with a ''dummy drug'' called a placebo to assess its effectiveness.

Randomised controlled trials – Randomisation is when people are allocated to the treatment group at random, usually by a computer programme. Neither you nor your doctor will be able to influence which group you are allocated to. This is done so that each group has a similar mix of people of different ages, sex and health.

Risks and benefits

Before you agree to take part in a clinical trial, all of the possible risks and benefits should be thoroughly explained to you, in order for you to make an informed decision regarding your participation.

What are the benefits of taking part?

There are many benefits to taking part in a clinical research study:

- You may have more check-ups
- You may receive a treatment that is only available in a clinical trial
- You may be helping doctors to improve cancer treatment for future patients

People who participate in studies sometimes feel that they are taking an active part in their healthcare and helping others.

What are the drawbacks?

Taking part in a clinical trial could come with some drawbacks. Such as:

- You may need to make more visits to the hospital / clinic than you would routinely do
- You may need to complete extra paperwork and have extra tests such as blood tests and scans
- You may experience side effects

What are the risks?

Some trials will have very little risk involved. However, when less is known about the treatment being tested, the risks maybe greater. In all trials the treatment may cause side effects. These may not be what you or the doctors were expecting; these may be unpleasant. However, you should be told everything that the researchers know about any possible side effects or risks and why the trial is being carried out, so that you can make an informed choice about whether to take part.

It is important to remember that not everyone involved in a clinical trial will receive a new treatment; some people will receive the current treatment. No one will know which is better until the end of the trial when the results are analysed.

What happens if I decide to participate?

If you do get approached about a study, it is important to remember that your participation is entirely voluntary. Your medical care will not be compromised in any way, and you may also withdraw at any time without an explanation.

If you do decide to take part, a member of the Oncology Research Team will make an appointment for you to come into the hospital or clinic to discuss the study.

During the appointment you will be able to ask any questions that you may have and raise any concerns. If you feel that you need more time to think about taking part, just let the nurse know. It is very important that you feel that you have had enough time to think and that all of your questions have been answered.

If you feel that you would like to take part in the study, you will complete a consent form – this is described as ‘informed consent’. You must give your informed consent to take part in a study; you cannot be entered into a study without giving your consent. It is important that you are satisfied that you have received enough information about the study to make an informed decision.

Once you have given your consent, the doctor or nurse will provide you with any trial related correspondence or medicines, depending on the study. They will also then discuss with you the next step.

What happens if I change my mind?

You can withdraw from a clinical trial at any time without giving a reason.

There are various reasons as to why patients sometimes change their mind about taking part in a trial. Whatever the reason, it is important that you contact the Research Nurse or Doctor as soon as possible so that alternative treatment options can be discussed. In this circumstance, you will usually be offered an appointment with your doctor so that they may discuss and arrange the most appropriate care for you.

For more information or to enquire about available Clinical Trials please contact the Oncology Research Team on Telephone 0300 707 3518 or 0300 707 2406

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