

- Clinical trials may not benefit you, but may improve cancer treatments for patients in the future.
- There may not be a trial available for you at the time when you need to change treatment.
- Some clinical trials involve extra tests and visits to the hospital. It may be possible to claim travel expenses for some of those visits. This varies from study to study, so please ask/discuss this with your research team.

Where can I get more information?

The cancer information centre, call: 0161 446 8100

www.clinicaltrials.gov

CRUK.org/trials

macmillan.org.uk/information-and-support/treating/clinical-trials

If you need information in a different format, such as easy read, large print, BSL, braille, email, SMS text or other communication support, please tell your ward or clinic nurse.

The Christie is committed to producing high quality, evidence based information for patients. Our patient information adheres to the principles and quality statements of the Information Standard. If you would like to have details about the sources used please contact the-christie.patient.information@nhs.net

For information and advice visit the cancer information centres at Withington, Oldham or Salford. Opening times can vary, please check before making a special journey.

Contact The Christie Hotline for urgent support and specialist advice
The Christie Hotline: 0161 446 3658
Open 24 hours a day, 7 days a week

Department of research

Clinical trials at The Christie

Introduction

The Christie is an international leader in cancer research and therefore you may be approached to take part in a research study or clinical trial. All information will remain entirely confidential and you will always be approached directly to take part in a clinical trial.

What are clinical trials?

Clinical trials are research studies that explore whether a medical approach, treatment or device is safe and effective for humans. Clinical trials produce the best information available for health care decision making. Clinical trials are one of the final stages of a long and careful research process and aim to find out if a new treatment or procedure is safe, has side effects, works better than the currently used treatment or helps you feel better. Research often begins in a laboratory where scientists first develop and test new ideas. However, an approach that works well in the lab still requires further testing in people. A clinical trial may find that a new approach, treatment or device improves patient outcomes, or it may offer no benefit, or it may cause unexpected side-effects. All of these results are important because they advance medical knowledge and help improve patient care.

Clinical trials can look at:

- risks and causes - how genetics, lifestyle and other factors can increase people's risk of cancer



- preventing cancer - using drugs or lifestyle changes to reduce risk
- screening - for people at higher than average risk or for the general population
- diagnosing cancer - new tests or scans
- treatments - new drugs or combination of drugs, new ways of giving treatment and new types of treatment
- controlling symptoms or side effects - new drugs or complementary therapies
- support and information for people with cancer

When or why might I consider a clinical trial?

The Christie is dedicated to making sure patients are informed and given the opportunity to take part in clinical trials. The trial may be offered to you at any point in your care, i.e. before or after surgery, when you are starting a new treatment, or if you have symptoms associated with your treatment or disease. Either you or your doctor may consider a clinical trial as a treatment option and we would encourage you to ask about suitable clinical trials at any time. This may mean giving you an additional treatment option to standard care.

You will always be offered 'standard', 'tried and tested' treatment if available, but researchers and scientists are striving to understand more about cancer and to develop new ways of managing the disease which may be better than 'standard' treatment and/or have fewer side effects.

Is it safe?

Your safety is very important to us. Before a trial is undertaken it goes through rigorous regulatory procedures. The doctors and nurses at The Christie are very experienced at conducting all types of clinical trials. The UK's Medicines and Healthcare products Regulatory Agency (MHRA) makes sure clinical trials meet high standards of practice and all our trials have to be approved by a research ethics committee. There are strict guidelines about who can take part and each trial has its own rules about which patients can or cannot be treated within the trial. There is always a small risk that the trial treatment may cause you to experience side effects that are unpleasant or unexpected. During the trial, the research staff will make every effort to minimise these risks. You will be closely monitored, which may mean a short or extended stay in hospital.

If I am offered a trial, what happens next?

Before you decide if you want to take part in a clinical trial, your doctor and research team will tell you about what is involved and what you will have to do if you choose to take part. You should feel that you have received all the information you need and be able to ask any questions. You may want to talk to your family or friends about the trial before making a decision. You will also be given contact details of the research team who will be happy to discuss any concerns you may have.

If you decide you want to take part in the trial, you will be asked to sign a consent form. You can't be entered onto a trial without giving your consent. Once you have given your consent the screening phase of the study begins. This usually involves some extra tests which enable the research team to confirm whether you are eligible to enter the study. If you decide not to take part in the trial or you give your consent to take part and then change your mind, you don't have to give a reason and this will not affect any future treatment or care.

Points to consider

- Information sheets may be long and complicated which may leave you feeling overwhelmed, but you will be supported by the research team.
- You may get access to new treatments or the same treatments given in a different way, that are not yet approved or funded for use on the NHS.
- It may provide an extra treatment option in addition to standard of care.
- Some trials include the use of a placebo which would not add any additional benefit to the treatment you are receiving.
 - The trial will involve a screening process that checks that it is safe for you to take part. This might cause a short delay in you starting your trial treatment. The result of screening may result in you not being suitable to take part in the trial.
 - It may involve more frequent or extra investigations such as blood tests, CT scans, biopsies which you may find reassuring, or may make you more anxious.
 - The trial drugs may be effective in stopping or controlling the cancer or preventing the cancer returning. In this case it may be possible for you to continue with this drug.