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NHS
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Research and Development Directorate

Early Phase Oncology Research Trials

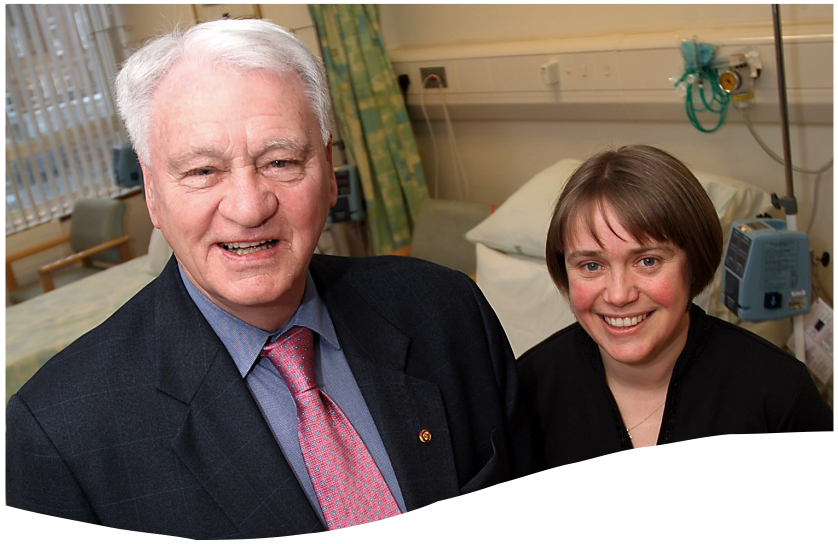
Helping your journey from the first appointment

Introduction

The aim of this guide is to help patients who have been referred to discuss taking part in an early phase trial at the Sir Bobby Robson Cancer Trials Research Centre.

The Centre is part of the Northern Institute for Cancer Research. It is a key Centre for experimental medicine, working with other research centres, universities and pharmaceutical companies.

Taking part in any trial is completely voluntary and you can withdraw your consent to taking part at any time, this will not affect your current care.



"I'm extremely proud that this Cancer Trials Research Centre is based here in my native North-East. I've no doubt that it is one of the best facilities of its kind, not just in this country, but in Europe."

Sir Bobby Robson

What is an early phase trial?

- How they work?
- Positives and negatives of early phase trials

What will happen at the first appointment?

- What will happen and who will I see?
- What questions should I ask?
- What will happen if there is no trial for me to take part in?

What will happen if you decide to take part?

- Stages of taking part in a trial
- Appointments and impact on time

A patient's journey

- A patients first-hand experience of taking part in an early phase trial
- A carers first-hand experience of supporting someone taking part in an early phase trial

Support

- Support whilst on a trial for both patients and family
- What happens to your GP when you are on a trial?
- Who manages your health whilst on a trial?

What is an early phase trial?

Trials are divided into different stages, called phases. The Sir Bobby Robson Centre concentrates on early phase trials called phase 1 and phase 2 trials. These are the earliest trials in the development of potential new cancer treatments using drugs found to have an effect against cancer cells in the laboratory.

Phase 1: They are usually small trials, recruiting only a few patients and may be open to people with any type of cancer.

When laboratory testing shows that a new treatment might help treat cancer, phase 1 trials are carried out to:

- Find out how much of the drug is safe to give patients
- Establish what the side effects are
- Find out how the body copes with the drug
- See if the new treatment has any effect on the cancer

Patients taking part in phase 1 trials often have advanced cancer and they may have had all the standard treatments available to them. The early phase trial offers new drugs to these patients.

Patients will be assessed in outpatients and by a research nurse at the research unit to make sure they have a certain level of fitness before joining a phase 1 trial. This involves procedures like blood tests, Electrocardiogram (ECG), measuring temperature, pulse and blood pressure. This can vary depending on the study.

Researchers monitor the effects of the new drug very carefully. That is why only a few patients are recruited at first on to a trial. They are given a very small dose of the drug and if all goes well under the supervision of researchers and a medical team then the next group of recruited patients are given a slightly higher dose of the drug. This continues until the highest safe dose is found.

Patients are reviewed very closely and they have large numbers of blood tests to find out how the drug is affecting them. Any side effects are recorded.

Patients will be asked to report to the research team anything that they feel has changed in their health while taking part in a trial

Advantages: Close monitoring by a medical team. Patients may benefit from the new drug and be able to continue using it after the research phase of the trial. Findings from the trial will help the discovery of new and more effective ways of battling cancer for future generations.

Disadvantages: The risks and side effects of the drug are not fully known or understood - it is not known if the drug will have any effect on your cancer. There will be numerous visits to the hospital for blood tests and examinations.

What are phase 2 trials?

Not all treatments tested in a phase 1 trial make it to a phase 2 trial. Phase 2 trials may be for patients who all have the same type of cancer or for patients who have different types of cancer.

Phase 2 trials aim to find out:

- If the new treatment works well enough to test in a larger phase 3 trial
- Which types of cancer the treatment works for
- More about side effects and how to manage them
- More about the best dose to use

They are often larger than phase 1 trials with up to 100 or so patients involved. Sometimes a new treatment is compared with another treatment already in use or with a placebo*. Sometimes researchers put the patients taking part into treatment groups at random so these trials may then be called “randomised trials”.

Phase 1 trials do **not include** the use of placebos. Some **Phase 2** may include a placebo.
***Placebos** - a substance that has no therapeutic effect, used as a control in testing new drugs.

Advantages: Close monitoring by a medical team. The treatment may shrink the tumour. Treatments that work will be tested in a larger phase 3 trial and benefit more patients and help future generations.

Disadvantages: Time consuming with hospital visits for blood tests and various examinations. Although the treatments have been tested in phase 1 trials there may still be side effects that the doctors are unaware of. The treatment may have no effect on the tumour.

Phase 1 trials
What dose of treatment is safe?

Phase 2 trials
Does the treatment work?

Yes

Phase 3 trials
Is it better than the current gold standard treatments?

Yes

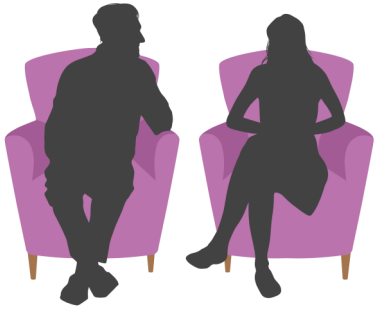
Phase 4 trials
Are conducted to identify and evaluate the long-term effects of new drugs and treatments over a lengthy period for a greater number of patients

What will happen at the first appointment ?

What will happen at your first appointment and who will I see?

You have received an outpatient appointment to attend the Early Phase Research Clinic at the Northern Centre for Cancer Care at the Freeman Hospital. At this appointment you will meet one of our research consultants.

During this appointment the consultant you see will review your medical history and assess you to get knowledge of your current health.



They will discuss with you the types of trials currently available and if you would like to take part. Through these discussions your consultant will be able to determine whether you may be eligible for any of the trials the unit has open or are currently in set up.

If you are happy to be considered for a trial you will be provided with a patient information sheet which will give you more information about the trial you could possibly be taking part in. You will also have the opportunity to visit the Sir Bobby Robson Research Unit and discuss the study in more detail with the nursing team.

Know what questions to ask: Below are some of the things you may want to ask when you have your first appointment. There is a notes section at the back for you to write down questions you may want to ask at this appointment.

It is important for you to get as much out of this appointment as possible and ask whatever questions you want. **There is no such thing as a silly question if you don't know the answer.**

Will I be expected to attend the research unit every week? It is worth asking about how long and how many visits the study you have been asked to go on has. Many patients feel it is important to know this, so they can organise family life and other commitments around their study appointments.

Will researchers have any idea beforehand about the likely side effects I may experience? In early phase trials this may not yet be fully understood, however your consultant and nursing team may still be able to advise you of potential side effects you may experience.

Restrictions on other therapies: In some trials you may need to stop taking certain alternative therapies or eating particular foods. The reason for this is that research may have shown these alternative therapies or food types interfere with the medication you may get as part of a trial. Please discuss this with your consultant if you are considering a trial.

Some trials require you to stop eating grapefruit

In some trials you may have to stop taking Saint John's wort

What will happen if there are no trials for me to take part in?

- There can be a number of reasons why there may not be a suitable trial for you to participate in.
- This could be down to your current medication, your current state of health, or simply we don't have any trials open that you are eligible to take part in.
- At this point your consultant will make you aware of why you are not currently suitable for a trial and offer you the opportunity to go on a waiting list.
- The waiting list is reviewed by the medical and nursing team on a weekly basis and patients will be contacted if a trial has opened that they are potentially eligible for.

What will happen if you decide to take part?

Early Phase Clinic

- Meet the research consultant
- Discuss your current health
- Discuss the possibility of taking part in a trial
- If there are trials you are potentially able to go on, you will be provided with a patient information sheet
- Have the opportunity to meet nursing team and have a look round the research unit

Support
You can be accompanied by friends or family during these hospital visits for support and also as a second pair of ears, which can be invaluable especially to catch information given out by doctors and research nurses.

Pre screening

- You may be asked at your initial appointment by the research team to consent to having your previous tumour biopsies used and additional blood samples taken at this appointment
- These biopsies and blood samples will be used to see if your tumour matches the profile for any of the trials running in the unit, results from these samples may take up to eight weeks
- Even after the results are back this does not guarantee you a slot on a trial
- **Not all trials need pre screening**

Informed consent

- At least 24 hours after receiving a trial patient information sheet you can contact the research unit and make an appointment to discuss being reviewed for the trial, or the research team can ring you if you prefer
- Once all your questions have been answered and you are happy to be reviewed, you and your research doctor will both sign a consent form

Screening

- After signing a consent form, you will go into the screening phase of a trial
- During this phase the team will ensure it is safe for you to take part in the trial
- This is done through a number of safety tests such as, having your blood, blood pressure and heart rate taken
- Sometimes patients will be asked to have scans taken. This may be done to confirm you are eligible for the trial and is also used as baseline information about your current health status

Treatment

- If all tests show it is safe for you to take part in the trial, you will then be allocated a slot, to start receiving the trial treatment
- Thereafter you are on the treatment phase of the trial where you will regularly attend the research unit to receive your treatment and be reviewed by the research nursing team and doctor

A patient's journey : A carers story

Cath's story

At the end of April 2013 my husband was told his cancer was inoperable. It was devastating news and very difficult to come to terms with. At that point we were told that he might be a candidate to go on early phase trial. We felt this was a lifeline, not necessarily a cure but certainly it would buy us some time. We attended an initial early phase clinic appointment not knowing anything about trials. Before attending this appointment we had decided that whatever was on offer we would probably take because we were desperate. You know, when you have come to the end of standard of care treatment it's a huge marker in the life of the carer and on the patient, particularly the patient and you want to do the absolute best you can in your remaining time.

Looking back on the journey with your husband, what information do you think would have helped?

At this point we didn't know anything at all about the trials, how long they would take, the likelihood of any kind of success or where you went for them. We were made aware of this information at this initial appointment and talked about his general health. We awaited the next stage which was to undergo pre-screening, some tests to make sure he was of a certain level of fitness and then we met up with some of the staff on the Unit who were fabulous and talked us through a very complicated patient information sheet.

How can future patients get the most out of this booklet?

We didn't have a booklet and googled a lot of information which can misinform patients. I would recommend reading this booklet before you come to your appointment. Being aware of what early phase trials are, what support is available and the practicalities of taking part in a trial are really important. I think it would have enabled us to talk about it without so many bits of guesswork and know what questions to ask. The information could have demystified that appointment and been a huge reassurance during a very stressful time. The booklet is readable and understandable, something to refer back to and that patients can give loved ones to read. I think it is a wonderful starting point on your entry into early trials.

So thinking back to that appointment and reflecting on what happened, what questions would you have asked?

I think we would have maybe asked if they had a particular drug in mind? Questions about chances of success with this drug? How often he would be expected to attend the research Unit? Was there a reasonable chance of added time to his life? Would a placebo be used, was that used in all trials? Would the research unit be totally responsible for his welfare and would there still be some links back to standard care if needed?

Looking back on your journey and now being aware of what support is available, what advice would you give future patients?

I would recommend taking a family member or friend for support as there can be a lot of information to take in. When we were on a trial, we didn't have access to the Maggie's Centre as it was just being built. Having been fortunate to visit the centre since, I am aware of the massive amount of supporting services that are free to cancer patients and are only a two minute walk from the research unit. Ask the nursing team about the supporting services that this area offers that can support your journey in a trial.

Are there any other comments you would like to make?

Always trust in the trials unit team and know that they are looking out for you. There is so much support there and everything is very well structured and thought out. You're not on your own and it gives you tremendous hope in a momentous part of your life. By taking part valuable information is acquired which will benefit future generations.

A patient's journey: A patient's story

Brian's Story

After my initial diagnosis I had courses of chemotherapy at my local hospital. I was told that my cancer was not curable and was asked if I would be happy to be considered for a clinical trial which I agreed to.

I was told by my consultant a number of weeks later that there was a trial at the Freeman Hospital that I could be suitable for. I agreed for my details to passed on to the Freeman Hospital research team, so an appointment could be made for me to discuss the trial further.

That day my consultant e-mailed the Sir Bobby Robson Unit, at the Freeman Hospital and was told it would be a number of weeks before I would be contacted to make an appointment. However, the same day my consultant rang me at tea time and told me that an appointment had been made for me to attend an outpatient appointment at the Freeman Hospital. It was explained that if I was successful in going onto a trial, the research team at the Freeman Hospital would take over my care.

I received a letter in the post giving me an appointment to discuss taking part in a trial. At the appointment I met one of the consultants who discussed my current health and a trial they had in mind that might be suitable for me. I was given an information sheet about the trial and a contact number. I wasn't anxious or worried about going to this appointment as I was reassured that I was in very capable hands, by my local hospital consultant. At the same appointment I was asked if I would be happy to give some blood samples and consent to some of my previous biopsies of my cancer being used to see if there were any treatments available based on my tumour Deoxyribonucleic acid (DNA).

Trial Journey

A number of weeks later I was contacted by the research team as there was a treatment option available within a trial that I was suitable for, but I still needed to go into the research unit to have some more tests done to confirm that I was able to go onto the trial. I had more blood tests, ECGs and Computed tomography (CT) scans. Initially the appointments were weekly or fortnightly for bloods, ECG, blood-pressure etc and every six weeks for CT scans. Once it was confirmed it was safe for me to receive treatment, I had treatment appointments every four weeks at the research unit, where I took a tablet.

Regular tests were done to check that it was safe to continue the treatment and if it's working by measuring the size of the tumour. This obviously involved quite a bit of time as I was driving from Billingham with my wife and daughter. After the first 12 months the appointments were reduced to once a month visits for bloods, ECG and treatment and roughly once every two months for a CT scan.

My biggest surprise throughout this journey into trials is that my initial thoughts were that it would only last three months. It is now past two years since I have been receiving treatment on the unit as part of a trial. And my treatment will continue, until it stops working.

What questions to ask, if you're thinking about going on a trial?

How much of a time commitment will it be?

How many times will you have to come to the unit and how long will the treatment last for?

What advice would you give?

My advice would be don't be scared to take part in a trial. The team at the Bobby Robson Unit keep a very close eye on you and take over your care from the GP. They are always there for you if you need any advice on your health or personal circumstances.

I found it very reassuring to be on a trial as the medical team and the nursing team keep a very close eye on your health. You get more scans than you normally would, which will show you what is happening with your cancer. Getting involved in cancer studies can potentially benefit you but will definitely provide future patients with better treatment options.

Support

Once you are enrolled into a trial, your GP will be sent a letter explaining what trial you are participating in and the contact details of the unit, should they have any questions about the trial.

If you have any questions before your appointment you can contact the research team through email
EPORT@nuth.nhs.uk

Who manages your health whilst on a trial?

You will be given a named nurse to contact at the unit, should you need any advice about your health. Once you have contacted the unit, the team will advise you if you need to be reviewed at the research unit, or go to your GP. You will be provided with a 24 hour emergency number, should you need any advice outside normal working hours.

An out of hours emergency contact

- The Acute Oncology Service offers an out of hours service to trial patients.
- This service is for patients who have any concerns or issues regarding their health while on a treatment within a trial.
- Your nurse will discuss this further with you and provide you with contact details, should you start treatment on a trial.

Overnight stay

Should the trial you are on require you to have a series of visits to the research unit, an overnight stay can be arranged.

Maggie's Centre Newcastle: The drop-in centre offers free practical, emotional and social support for patients with cancer and their family and friends. Website: www.maggiescentres.org
Tel : 0191 233 6600.

Macmillan Centre: Is a drop-in centre, based in the oncology outpatients department at the Freeman Hospital beside the research unit. It offers information and support, where patients affected by cancer can discuss cancer diagnoses, treatment options and practical issues relating to cancer Tel: 0191 213 8611

Complementary therapy

The complementary therapy team, based in Northern Centre for Cancer Care offers a range of services such as massage, aromatherapy, gentle touch and relaxation sessions which are available to all patients on the Sir Bobby Robson Cancer Trials Research Centre. To make an appointment speak to a member of nursing team or call 0191 213 8485 / e-mail: ComplementaryTherapyTeam@nuth.nhs.uk

PALS

As a patient, relative or carer sometimes you may need to ask someone for on-the-spot help, advice and support. This is where the Patient Advice and Liaison Service (PALS) comes in. PALS provide confidential advice and support, helping you to sort out any concerns that you may have about any aspect of NHS care. Tel: 0800 032 02 02
e-mail: northoftynepals@nhct.nhs.uk

Notes
Please use this space to note down any additional questions you may wish to ask your consultant or nurse at your early phase trial appointment:

Please remember to bring a list of your current medications to your appointment.