Royal National Orthopaedic Hospital NHS
NHS Trust

Guiding Chordoma Treatment Through Molecular Profiling: A National Cohort Study

Participant Information Sheet for Adult Participants

Chief Investigator: Professor Adrienne M Flanagan
Sponsor: Royal National Orthopaedic Hospital NHS Trust (RNOH)

You are invited to take part in a research study involving chordoma. Before deciding to take part, please read the following information to understand why the research is being done and what it will involve. Please take your time to read the information carefully and talk to others about the study if you wish. If you have any questions or concerns, please do not hesitate to contact us.

Why have I been invited?

You have been invited to participate in this study because you have been diagnosed with a chordoma. Your doctor should have explained this condition to you.

What is the purpose of this study?

Chordoma is a rare cancer that starts in the bones, affecting about one in a million people. Unfortunately, very little is known about this disease and we need to gather information to understand this disease better. We would like to collect information about the tumour, your experiences and the treatments you have had over a period of time.

The aim of the study is to improve the outcome of patients with chordoma, and in the long term hopefully develop new treatments. As part of this, we would like to study the tumour samples which are removed if you have an operation. The research will include genetic analysis of the tumour tissue to allow us to understand why and how the tumour grows.

In addition, we would like to establish if a new blood test can tell us if the chordoma has grown back. The earlier we know if a tumour has grown back, the more likely we will be able to treat it. To investigate this, we will require blood samples to be taken from you every 3 to 6 months for the next five years.

Do I have to take part?

No, it is entirely your decision if you want to take part. It won't affect your treatment or future care if you decide not to take part in this study.

What will I have to do?

You will be asked to sign a consent form that allows:

- your clinical information to be obtained from your notes and imaging (x-rays and scans) from any hospitals that you have attended in the past or will attend in the future.

- your clinical information to be stored on a secure database in a coded / anonymised form. This means that it will not be possible for you to be identified on this database.
- us to use and store a small amount of tissue that was taken from your tumour for analysis.
- us to give you a questionnaire to fill in which looks at how chordoma affects your life
- us to perform research studies including genetic analysis on your tissue samples.
- us to ask you for a blood sample of 20-30 ml (5-6 teaspoons) every 3-6 months for the next five years. Blood tests will be taken at hospital appointments or at your GP surgery, whichever is more convenient for you.
- us to offer follow up appointments for up to 5 years. However, you can withdraw from the study at any time you want. It will not affect your future care or treatment if you decide to withdraw from the study.
- us to transfer your clinical information, blood samples and tissue samples to an existing ethically-approved biobank after the study is completed.
- us to involve NHS Digital (a government body that deals with clinical data) so that we can find out if something significant happens to you, for instance, if you have been admitted to hospital, or a death has been registered.

What will happen to my samples?

Samples that are not used for your clinical care will be stored and used for this research project. Some tissue you donate may be used in research involving laboratory animals and this is strictly regulated by The Home Office. Research may be conducted in the UK or overseas. However, only researchers who have ethical permission to use the tissue will be given access to your samples. You will not be identifiable to the researchers.

Samples left over after this study will be held in a biobank for future research projects. Any new research projects will require separate ethical approval. To offset some of the cost of running the biobank, researchers may have to pay an administrative charge.

What are the possible benefits of taking part?

There are no direct advantages to you, but it may help others in the future if you participate in this study. Unfortunately, we will not be able to pay you. The tissue and blood samples are a gift to the research project.

What are the disadvantages of taking part?

As far as possible, each blood test will coincide with your hospital appointments. Nevertheless, we appreciate this can be inconvenient. You may perceive some discomfort or bruising from taking the blood sample but not more than a normal blood test.
All members of the research team will have undertaken training in information governance; good clinical practice and have knowledge of the Human Tissue Act.

What will happen to the results of the research study?

The results of the study will be published in medical journals and presented at international medical research meetings. It will not be possible to identify you in any publication or presentation. The results of the study will also be published on the Bone Cancer Research Trust website, (https://www.bcrt.org.uk/), The Chordoma Foundation website (https://www.chordomafoundation.org/), and the Chordoma UK website (http://chordoma-uk.org/).

Results from the study are not directly reported to you. However, unexpected findings that may have an impact on your treatment will be reported to your clinical team. They will then contact you as appropriate to discuss this.

What if I don't want to carry on with the study?

You can change your mind at any time. This means that researchers will no longer collect data and tissue from you. However, data and tissue already collected with your consent would be retained and may be still used in this study.

If you do not want to be part of this study anymore, please tell your doctor or contact the study team:
Department of Histopathology
Institute of Orthopaedics and Musculoskeletal Science
Royal National Orthopaedic Hospital
Brockley Hill
Stanmore
Middlesex
HA7 4LP

E-mail: biobank@rnoh.nhs.uk
Telephone: 020 8909 5354

What if there is a problem?

If you would like further information or you have concerns about this study at any time you can:

- Discuss it with your doctor or nurse
- Contact the study co-ordinator and chief investigator (Professor Flanagan) on 020 8909 5354, who will answer your questions or will arrange for you to speak to an appropriate person.
- If you would like to speak to someone independent of the research team, contact the Patient Advice and Liaison Service (PALS): pals@rnoh.nhs.uk or 020 8909 5439 / 020 8909 5717.

In the unlikely event that something goes wrong and you are harmed due to negligence during the research, you may have grounds for compensation and can take legal action against the RNOH. However, you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Will taking part in this study be kept confidential?

Yes. All information about you, your tissue and blood samples will be treated in the strictest confidence. Your identifiable data will be shared only with the Study Coordinator at the main site who will assign you a study Identification number (ID). This unique study ID will then be used to label your samples from which no information about you can be traced back by the researchers.

Before having access to your clinical information and/or tissue samples researchers must agree to conditions that safeguard your confidentiality.

The role of your General Practitioner (GP) / family doctor

In case you are unable to come to a hospital appointment we will ask your GP to take blood samples. On these occasions you will be given a letter for your GP so that she/he knows that you are participating in this study.

Who is organising and funding the research?
This study is funded by The Bone Cancer Research Trust, Chordoma Foundation, Chordoma UK, and University College London Hospitals (UCLH) charities.

Who has reviewed the study?
To ensure that the research is of high quality it has been reviewed and approved by expert scientists.

All research in the NHS is reviewed by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by London - Bromley Research Ethics Committee.

Who do I contact for any information about research projects?

You can contact the R&D office via research@rnoh.nhs.uk or 020 8909 5529

Who do I contact for specific information about this research project?

You can contact the study team via biobank@rnoh.nhs.uk or 020 8909 5347.

If you decide you would like to take part then please read and sign the consent form. You will be given a copy of this information sheet and the consent form to keep. A copy of the consent form will be filed in your patient notes, one will be filed with the study records and one may be sent to the Research Sponsor.

Thank you for taking the time to read this information sheet and to consider this study.