EPCTU

early phase clinical trials unit

Giving our patients tomorrow's treatments today

Welcome to the Early Phase Clinical Trials Unit (EPCTU)

The Early Phase Clinical Trials Unit (EPCTU) aims to support the translation of research findings in to clinical practice.

This booklet includes an introduction to our team and details of how to find and contact us at the Churchill Hospital in Oxford.

We have a you tube video explaining what we do on the unit, please see link below:

https://youtu.be/Zl94VBlFrtY

Or go to CRUK Oxford Centre website and scroll to the bottom of the page and they are available there: https://www.oncology.ox.ac.uk/research/srf/early-phase-clinical-trials-unit

If you have any questions or suggestions on how we could improve the unit, please let us know.

Simon Lord
Clinical Director

Caroline Miles
Senior Research Nurse

All photographs taken before COVID-19 safety measures introduced in 2020

Opening Hours:

Monday to Thursday	7.30am – 10.00pm
Friday	7.30am – 6.00pm

Closed weekends and Bank Holidays.
Occasionally appointments may occur outside normal working hours

Contact numbers:

Early Phase Research Office	01865 235469
Early Phase Clinical Trials Unit	01865 235015/6

These telephone numbers are answered 24/7.

Your first appointment

Once your oncologist has referred you to the EPCTU, we will invite you to meet a member of our research team. This first appointment can be conducted over the telephone or via a video link, or face to face in the Outpatient Department at the Churchill Hospital.

We will discuss your medical history and general health and explain the principles of Early Phase studies. You can read more about this on our website or in the Q&As at the end of this leaflet.

After your first appointment

After your appointment, take some time to decide if you want to go ahead with a clinical trial. If you would like to enter a trial, we can add your name to our Trials Waiting List.

As soon as a suitable study becomes available, we will contact you by phone and arrange to give you a Patient Information Sheet in person, by post or by email. This will give you specific details about the study we are aiming to recruit you to, such as the type of drug that is being tested, the way it is given and the number of visits you will need to make during the study.

Consent visit

Once you have had time to read the information sheet and discuss it with your friends and family, we will give you an appointment at the EPCTU at the Churchill Hospital.

At this visit you will meet the trials team and your allocated study nurse, and you can ask questions.

Please do not arrive earlier than your allocated time. If you are going to be late, please call the Early Phase Research Office to let us know.

During your visit the trials team will discuss the details on the information sheet with you, and invite you to give your consent to enter the study. We will then conduct a series of 'screening investigations' such as CT scans, blood tests, urine samples and ECGs to ensure you are eligible. These are usually conducted on the same day and over the next couple of weeks.

Taking part in the trial

Once you have enrolled in a trial, your appointments will need to be at set times – we will explain this during your consent visit. By consenting to the trial, you consent to making yourself available at the set times when we need to see you.

Travel to the Churchill Hospital

For information about travel to the Churchill Hospital and facilities on the Churchill site, please visit:

www.ouh.nhs.uk/hospitals/churchill

Travel expenses

If you are enrolled in a clinical trial, you may be eligible to claim some travel expenses, especially if you live outside Oxfordshire. Please ask your research nurse for details.

Going to other departments

We may ask you to visit other locations for tests, scans or specialist advice. Some of the studies will require you to visit the Manor Hospital, a private hospital nearby, for scans.

Oxford University Hospitals NHS Foundation Trust has specialist departments split across our different sites. Cardiology (heart), Audiology (ears) and Ophthalmology (eyes) are based at the John Radcliffe Hospital. Some studies will require visits there.

If necessary, we may use a local optician, called Gardiners, for some eye tests.

We will let you know in advance if you need to travel to another location. If you need help to travel for appointments, please speak to a member of the team.

Please ask us for a map showing the route between the EPCTU and the other departments that we use.

What to bring when taking part in a trial

Depending on the nature of the trial we may ask you to remain on the unit for long periods of time, to have various blood tests and other observations. In some cases, you may need to remain on the unit all day.

We offer free WIFI, and you are welcome to bring portable devices such as tablets and laptops, along with books and magazines etc.

For more information about your visit to hospital, please visit:
www.ouh.nhs.uk/information

Overnight stays

Some trials require patients to stay overnight – we will tell you this before you give your consent to take part in the trial.

If we need you to stay overnight, we will admit you to our Oncology or Haematology Wards, depending on your diagnosis.

It is likely that you will share a room and bathroom with other patients, in either a four or two bed bay.

You will need a negative CoviD-19 swab test result before we can admit you. Your research nurse will arrange an appointment for this.

EPCTU Staff

Research Nurses

Each trial has a research nurse allocated to it, and every patient in our trials will have their own research nurse.

They are in charge of the day-to-day running of trial, managing appointments, arranging tests as required and ordering the study drugs. In the background, the research nurse is responsible for ensuring that the research is conducted to the very highest of standards to enable safe and clear results to be drawn from the trial.

Research nurses have to know the trial protocol and ensure instructions within it are closely followed. They make sure that clear and concise documentation of each visit and procedure is captured in a timely manner and gathering of data is both accurate and meaningful.

Your research nurse will assess your needs regularly and can refer you to other professionals, such as dietitians, physiotherapists, counsellors, palliative care, occupational therapists etc. Please ask your nurse for more details.

Research Staff Nurses

The research staff nurses are based on the EPCTU. They perform the day-to-day tasks the study requires.

Their responsibilities include recording of observations, phlebotomy (taking blood), cannulation, trial sample collection and processing, and accurate and timely documentation. These nurses work closely with and under the guidance of the research nurses on a daily basis to provide expert care to our patients.

Clinical Research Fellows

The clinical research fellows are doctors who are training in Oncology or Haematology, and are affiliated to the EPCTU. They are responsible for evaluating patients' suitability for taking part in early phase clinical trials upon their initial referral, and provide information to potential patients about trials that they may be able to take part in.

The doctors work closely with the research nurses to organise appointments and address any ongoing issues patients may have once enrolled. These doctors take consent and then evaluate the patients' progress during their participation. They will also refer patients on to other specialist services if appropriate.

Consultants

We have four consultants who lead the EPCTU, three of whom are Medical Oncologists (specialists in drug treatments for cancer) and one a haematologist.

They provide expert advice on the day-to-day management of patients on early phase clinical trials, and also lead many of the clinical trials that we run. However, other consultants with the department of Haematology and Oncology in Oxford may also lead clinical trials in EPCTU.

Our consultants:

Professor
Sarah Blagden

Dr Graham Collins

Professor
Mark Middleton

Dr Simon Lord

Compliments, comments and complaints

Oxford University Hospitals NHS Foundation Trust is committed to providing the very highest standards of care. We like to hear about the things we have done well, as well as the things we could do better. We will always try our best to get things right, but sometimes mistakes happen. When they do, it is vitally important to put things right as soon as possible, and to ensure that the same mistakes do not happen again.

If you have a concern about your care or treatment, or about any of our services, please talk to the member of staff who is with you at the time; they will be as helpful as possible and may be able to resolve your concerns straight away. If you prefer, you can submit feedback using the paper and envelopes provided in the corridor of the unit.

If you would like to speak with a senior member of staff, please contact our senior research nurse Caroline Miles on 01865 235242.

Waiting on the unit

We aim to see all our patients as quickly as possible, but sometimes being enrolled on a trial means that you will have to wait on the unit for a period of time.

Blood tests

These can take a few hours to be processed. In order to keep our patients safe we may need to wait for these results before going ahead with administering a study drug. Depending on the blood test results, treatment may need to be delayed or stopped and/or we may need to give you supplements before we can continue.

Study drug production

Most of our study drugs are prepared at the Churchill Hospital by our pharmacist in the Aseptic Unit. The study drugs have various expiry times from when they are prepared, some may last a few days, others just a few hours. For some trials, the pharmacists are not able to make the study drug until blood test results are back, determining whether the patient is able to go ahead. It may take two to three hours for your study drug to be ready following your blood results.

Observations to ensure your safety

Sometimes we need to ask patients to remain on the unit for observation following administration of the study drug. This can potentially be for up to 12 hours after the drug is given. This is both a safety measure and a means of collecting more important data about the study drug.

In each trial protocol it states when we need to collect samples, do vital signs, ECGs etc. These have to be done at certain time points and it is vital that we follow this as closely as possible.

When to contact us

Most trial drugs can cause unwanted reactions, known as side effects. You must report any side effect you experience while on a trial. Please refer to your patient information sheet for details of the specific side effects of the trial drug/s.

Call us immediately on the number on your patient information sheet, or call 999 if advised, if you experience the following symptoms:

- Chest pain
- Difficulty breathing
- Generally unwell
- Shivering episodes or flu like symptoms
- Temperature above 37.5OC or below 36oc
- Being sick (vomiting)
- Diarrhoea four or more times in 24hrs
- Swollen or painful legs
- Sore mouth that makes eating and drinking difficult
- Bleeding or unusual bruising

Call us on the EPCU numbers provided within 24 hours if you experience the following symptoms:

- Itching or painful skin changes/rash
- Sore watery eyes
- Increased pain
- Constipation
- Nausea (feeling sick)
- Diarrhoea (two to four loose stools / bowel movement in 24 hours
- Sore mouth, but able to eat and drink

Please monitor the following symptoms, and report if things get worse:

- Tiredness
- Skin changes that are not itching or painful
- Mood changes
- Difficulty coping with the treatment
- Loss of appetite

These are a guide – with clinical trials there is always the possibility of coming across side effects which have not yet been seen.

If you feel a change in yourself from normal, please contact us on the phone numbers provided:

01865 235469

01865 235015/6

Our partners:

The partnerships that make research happen here in Oxford:

Cancer Research UK Oxford Centre

The Cancer Research UK Oxford Centre brings together the expertise and resources of partner organisations in the fields of cancer treatment and clinical research. The centre was established in close partnership with Oxford University Hospitals and has links to other trusts conducting cancer research in the Thames Valley.

www.cancercentre.ox.ac.uk

Cancer Research UK (CRUK)

CRUK has a unique and pivotal role in cancer clinical trials in the UK. As well as funding doctors and nurses who lead the trials they provide essential UK wide support to ensure the trials run smoothly. CRUK spend nearly £22 million pounds every year on research in Oxford bringing together teams from Oxford University Hospitals and University of Oxford departments.

www.cancerresearchuk.org

Oxford University Hospitals
NHS Foundation Trust

Oxford University Hospitals NHS Foundation Trust (OUH)

Oxford University Hospitals is a world-renowned centre of clinical excellence and one of the largest NHS teaching trusts in the UK. Our collaboration with the University of Oxford underpins the quality of care that is provided to patients, from the delivery of high quality research, bringing innovation from the laboratory bench to the bedside, to the delivery of high-quality education and training of doctors. Existing collaborations include the ambitious research programmes established through the Oxford Biomedical Research Centre.

www.ouh.nhs.uk

Oxford Biomedical Research Centre
Enabling translational research through partnership

Oxford Biomedical Research Centre (BRC)

At the Oxford BRC research is divided into 14 themes. This includes the speciality of cancer. The work carried out here is called translational research which means its focus is on ensuring that new findings translate into improved patient care.

oxfordbrc.nihr.ac.uk

ecmc
Experimental
Cancer
Medicine
Centres

Oxford Experimental Cancer Medicine Centre (ECMC)

The Oxford ECMC aims to apply basic scientific discoveries in cancer biology to the development of novel cancer therapies to help individualise patient care. The centre has expertise in immunology, DNA repair, angiogenesis and molecular pathology.

www.ecmcnetwork.org.uk

Medical Oncology Ward Charitable Fund

We have a fund held by Oxford Hospitals Charity which we use for patient and staff welfare. This is used for items such as additional equipment for patient comfort and entertainment, and staff training and team building.

If you have any ideas, particularly about patient welfare, and what you would like to see more of on the unit, please let us know.

If you would like to make a donation please do so in one of the following ways.

Cheques payable to Oxford Hospitals Charity - Medical Oncology Ward

Send to:

Oxford Hospitals Charity
Unipart House
Garsington Road
Oxford OX4 2PG

Call **01865 743444**, stating that you would like your donation to support the Medical Oncology Ward Charitable Fund.

www.hospitalcharity.co.uk

Other funds

Although some of the trials we run on the unit have commercial sponsorship, a large proportion of our work is funded through charitable donations. We will be happy to discuss which charities we are currently working with.

Psychological support in Early Phase Trials

The Early Phase Trials team is supported by several services in order to provide a wide range of psychological and emotional treatment.

Please talk to your research nurse at any time if you feel you might benefit from any of the below or if you simply want to discuss potential options.

Maggie's

Monday to Friday 9.00am - 5.00pm

01865 751882

- Walk-in service for mobile patients and their families
- Financial (including holiday insurance) and emotional support
- Tai chi, art therapy, mindfulness. Patients can also be referred for counselling sessions.
- They run a specialist session for patients considering clinical trials
- Other specialist sessions include "coming to terms with completion of treatment". This can be helpful for people coming off study or coming to the end of trial treatment who are struggling to return to a life without the routine of the trials visits and regular medical reviews.

We are also supported within the hospital by our palliative care inpatient nurses and our local hospice:

SOBELL HOUSE

Sobell House

24 hours

- Sobell House offers physical, psychological, social and spiritual care to those facing life-threatening illness, death and bereavement. The focus is on quality of life, respecting the uniqueness of each person, and respect for the dignity of all users of the service
- Based on site a few minutes' walk from the main entrance
- Main focus is on symptom control
- Admission to Sobell House requires discussion with the nursing and medical team
- Covers Oxford up to the Berkshire border including Carterton, Wantage, Didcot, Abingdon, Watlington, Wheatley, Wallingford etc., but not Chipping Norton

Further support

maggie's

Maggie's Centre, Churchill Hospital

Maggie's Centre provides information and support to address every aspect of living with cancer – from the practicalities of claiming benefits, to the physical and emotional effects that people might be experiencing.

Open Monday to Friday 9.00am - 5.00pm

No appointment necessary, just pop in for a cup of tea.

Tel: 01865 251882

www.maggiescentres.org

Carers Oxfordshire

Carers Oxfordshire listens to carers and provides information and advice. It also aims to help carers get the support they may need.

Tel: 0845 050 7666

www.carersoxfordshire.org.uk

Macmillan Cancer Support

Macmillan Cancer Support is a UK charity supporting people with cancer and their families with specialist information, treatment and care.

www.macmillan.org.uk

Cancer Research UK

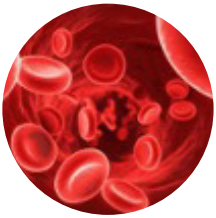
Cancer Research UK provides patients and health professionals with information on lifestyle, cancer and current research.

www.cancerreserachuk.org

OUH Haematology website

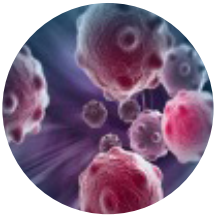
Information for patients and relatives

www.ouh.nhs.uk/haematology



OUH Oncology website

www.ouh.nhs.uk/cancer



We appreciate that some of our patients come from other areas, so please feel free to ask and we will find information about services in your local area.

Social media, blogging and photography

We are aware that many of you share your experiences via social media and blogging. Whilst we are happy for you to do this, **we ask that the unit is not identified, nor any of the staff members by name.**

Photography and filming is not allowed anywhere on the Churchill Hospital site without the permission of the Oxford University Hospitals NHS Foundation Trust's Communications team.

Transport and travel claims

Taking part in an early phase clinical trial often involves more visits to hospital than if you were receiving standard NHS care.

The timing of these visits is often set by the trial schedule. We recognise this can be difficult and we ask that you carefully consider how you will make your way to and from the hospital before you agree to take part in the trial.

It is your responsibility to arrange your transport.
If you have any concerns or problems surrounding your transport arrangements, please tell your research nurse at the earliest opportunity.

You may make your way to the hospital via public transport, driving yourself or being driven. You will be able to claim your travel expenses but only for journeys specifically related to the trial.

The maximum you may claim per visit is **£60**, although this can vary from trial to trial – please check with your research nurse.

We will give you a form to complete so we can pay the money into your bank account, and your research nurse will give you a travel claim form and explain how to fill it out. It may take up to eight weeks to receive your payment.

Glossary of terms

Principal Investigator (PI)

The doctor responsible for your trial.

Consent Form

You sign a consent form before we perform any trial related tests.

Protocol

A lengthy document which explains the purpose of the trial in great detail and outlines the procedures and instructions for the medical team and nursing staff to follow.

Inclusion / Exclusion Criteria

Key standards that people who want to participate in a clinical study must meet.

Trial Drug / Investigational Medicinal Product (IMP)

This is the medicinal drug which we will administer to you. It may be a new drug which has not been given to a human before, or it may be a licenced drug which is being used in combination with an unlicensed drug. Trial drugs can be given orally (tablets), intravenous (IV through the vein), subcutaneous (injection under the skin), intramuscular (injection into the muscle), or intratumoural (injection into the tumour).

PKs / Sample Handling (SHL) blood tests

Blood samples taken specifically for trial purposes by a research nurse at specific time points and they provide vital data for clinical trials.

Adverse Events

We don't often know what side effects you will experience from the trial drugs and therefore we ask you to inform us of any adverse events you experience. It is important that you inform us of side effects either on your clinic visit or over the phone.

Toxicity

Toxic side effects caused to healthy cells, by cancer treatments.

Amendment

A written description of a change or formal clarification to the trial, this may mean you need to re-sign a new consent form for the trial.

Purple Book

We will give you a purple book to carry with you at all times. This includes information about which trial you are on, who your research nurse is and who the PI (Doctor) for your trial is. Your research nurse will also enter all your appointment dates and blood results in this book. This booklet has all of the contact phone numbers should you feel unwell and need to telephone us.

Follow-up

We will see you at regular intervals to observe the effects of trial drugs and for data collection once you have finished the trial.

Frequently Asked Questions

Question 1: What kind of studies does the EPCTU run?

A: We run trials of new anti-cancer treatments that are delivered intravenously (IV), by injection into tumour or in tablet form.

Question 2: Will I be given a placebo?

A: No, the vast majority of the studies we run are non-placebo trials so all participants will receive active drug

Question 3: How long will the study last?

A: This depends on the specific study you enter, but most of our studies continue for as long as they benefit you.

Question 4: Will I know if the treatment is benefitting me?

A: We will conduct regular assessments of your cancer while you are on a study, using blood tests and CT scans (or MRIs). If there is evidence that your tumour is growing significantly or you experience side effects that cannot be reduced by lowering the dose of the drug, you will stop participating in the study.

Question 5: What happens if I have to stop participating in a study?

A: Once you stop the study we will re-evaluate your health and discuss whether you are suitable for another study or whether your oncologist has another treatment that is suitable for you.

Question 6: What happens if you give me information about a study but I don't want to enter it?

A: You are not under any obligation to enter a trial. If you do not want to enter a study, or if you decide to stop participating in a study, we can discuss other studies that might be preferable.

Author: Laura Davey (RN) with help from all the nurses on the EPCTU
May 2023
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