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Patient Information Sheet 1 (PIS1)

(Consent step 1)

Version 4.0, Date: 11th September 2019

Information for patients eligible for registration into the FOCUS4 Trial Programme in colorectal cancer

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1 Why am I being given this patient information sheet?

You are being invited to take part in a research study called FOCUS4, because your oncology doctors are recommending or have already started you on a course of treatment for colorectal (bowel) cancer.

Participation in the research is entirely voluntary. If after considering it, you decide not to participate, this will not affect your care in any way and your oncology doctor will explain the best alternative standard treatment available.

2 Why am I being asked to participate in this research?

When cancer of the bowel is not completely removable by surgery or when it has spread to elsewhere in your body, treatment may be given. This is a form of drug treatment which aims to kill cancer cells. Your oncology doctor is recommending that you have around 16 weeks of treatment to try and stabilise or reduce the size of your tumour.

Usually, the type of treatment that is offered to a patient depends on how well it works on average in patients with bowel cancer.

However, there are now some specific tests that can be done on the tumour which may help us to choose more accurately which sort of treatment might be best for you when you reach the end of your initial treatment.

After the end of your initial treatment, we will offer you entry into a trial of a new form of treatment for your specific type of bowel cancer.

3 What am I being asked to consent to?

To take part in this research study you will be asked to consent to two separate steps. We have provided a flow chart at the end of this information sheet to show the steps more clearly. The first step is explained here and step 2 is described in section 5 of this information sheet.

Step 1 asks for your permission to send a piece of your tumour (already stored in the local hospital pathology department where your cancer was diagnosed) to a central laboratory. A copy of your consent form will be sent to your local hospital pathology department (where it will be kept in a secure location), to authorise the release of your pathology block to the central laboratory.

This central laboratory will run specific tests (known as 'molecular markers') on the tumour sample. These tests will identify your cancer into a 'sub-type'. This process will take several weeks. In a few patients (about 2%), the tests do not work properly and the tumour is considered as unclassified. These test results will be made available to your oncology doctor for this research study. However they may help determine whether there are other future studies that you should consider following your participation in FOCUS4.

Following the specific tests, we would like your permission to store the piece of your tumour that was used to perform these tests. It will be stored at a central laboratory to be used for other studies for future bowel cancer research. This research will help us understand more about bowel cancer and the type of treatment that might be more effective for other patients in the future. It will involve extracting DNA or other material from the piece of your tumour. This research is based in UK Universities but may involve collaboration with commercial companies or other institutions.

All such work is anonymous: your specimens will be identified by your unique trial number, not your name. These additional studies will

not affect your treatment in any way, and you are free to withhold this permission without affecting your participation in FOCUS4 or your relationship with your doctor.

In addition to the blood samples that will be taken as part of your standard care, we would also like your permission to take some further blood for other bowel cancer research purposes. This will help us find substances in your blood which might help us understand more about bowel cancer and the type of treatment that might be more effective for other patients in the future. It will not help us with your own treatment. There are two types of blood sample collection required for two different areas of bowel cancer research. One area of research just requires one blood sample. The other requires a sample at the start and some additional samples later during the study. Your consent form will ask whether you are happy to provide the initial blood samples for these areas of research. We will ask you in the second stage of the trial about the later samples.

A copy of your consent form will also be sent to the Medical Research Council Clinical Trials Unit at University College London (MRC CTU at UCL) who are responsible for running this trial. They will destroy their copy of the consent form once they have checked it.

We are also asking if we may collect future routine information about your health status after participation in the trial.
This will be collected by adding your name to government national registers such as the Office for National Statistics (ONS) and the NHS Strategic Tracing Service. The MRC CTU at UCL is registered to store this information according to the requirements of the UK Data Protection Act (DPA). There is a question about this on the consent form that we will ask you to sign before you agree to be registered into FOCUS4.

4 What will happen to me during my initial treatment?

Your initial treatment will include a course of standard treatment as recommended by your oncology doctor. It is routine practice to see how the tumour is responding by having a CT scan and this will be arranged about half way through, and again at the end of your initial treatment. CT stands for computerised tomography. The CT scanner uses X-rays to take a series of very detailed pictures of the body and is a painless procedure. The pictures are taken while you lie on a couch, which moves backwards and forwards through the hole of the machine.

This procedure involves some exposure to ionising radiation. Like all medical procedures, this does entail some risk. Ionising radiation can have an adverse effect on the body, including a small increased risk of other cancers at a later date. However in this case the benefits outweigh any such risk. It allows your oncology doctor to see how your cancer is behaving more regularly. So they are able to detect if your cancer has grown as early as possible.
If the CT scan half-way through your initial treatment shows that you are responding to the treatment (your cancer has not grown or even shrunk), you will continue on treatment to

around the 16 week CT scan. If your tumour has got bigger at this half-way scan, your oncology doctor will discuss with you about other treatment options at that time.

5 What will happen to me at the end of my initial treatment?

The second step of this research study will start at the end of your initial treatment when we will have the results of your specific tests back from the central laboratory. If at the end of your initial treatment, your cancer has shrunk or at least not grown, for many people this would be a time when they might take a break from the treatment. In our last trial called The COIN Trial we showed that having a break from treatment after this initial course of treatment, is a safe thing to do for most patients.

The aim of the FOCUS4 study is to find a good treatment for your particular type of cancer after you have finished your initial treatment. We will be doing it by testing how patients get on with a new treatment tablet compared to a dummy tablet or active monitoring.

The new treatments that we will be testing will be selected because they may offer a possibility of benefit for patients with the type of bowel cancer that we will identify by your specific tests.

When we know the results of your specific tests, we will provide you with more detailed information on the trials that will be available to you at that time. Please look at the flow chart at the end of this information sheet to see where step 1 ends and step 2 starts.

If you want to get information on all the trials that we will be conducting, we can provide you with patient information sheets for all of them now, but we feel it would be easier for you to wait until we know the results of your specific tests and give you the relevant information at that time.

6 What will happen to the information collected about me during my initial treatment?

University College London (UCL) is the sponsor for this study, based in the UK. UCL will be using information from you and your medical records in order to undertake this study and will act as data controller for this study. UCL will be responsible for looking after your information and using it properly and will keep identifiable information about you for 25 years after the study has finished.

Your rights to access change or move your information are limited as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information at:
www.ctu.mrc.ac.uk/general/privacy-policy

How will your data be stored and collected?
Your hospital will collect information from you and from your medical records for this research study in accordance with our instructions. They

will use this information as needed for your care. Your hospital will use your name, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. UCL will collect information about you for this research study from your hospital. This information will include health information, which is regarded as a special category of information. We will use this information to conduct our research. This information is supplied via electronic and paper forms designed to collect the study information.

Certain individuals from UCL, and regulatory organisations may look at your medical and research records to check the accuracy of the research study.

Your hospital will pass your NHS number, name (if consent is provided) date of birth and pathology number to UCL along with the information collected from you and your medical records. Where information could identify you, the information will be held securely with strict arrangements about who can access the information. The people who analyse the information will not identify you.

UCL will keep information about you for a minimum of 25 years after the study has finished.

Where information could identify you, the information will be held securely with strict arrangements about who can access the information.

How will your data be used in future / other research?

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the relevant legislation, ethics and research policy requirements.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

You can find out more about how we use your information at:

www.ctu.mrc.ac.uk/general/privacy-policy.

7 What if I do not want to participate in one of these trials after the end of my initial treatment?

By consenting to sending your piece of tumour for specific testing, you are under no obligation to consent to participate in any of these trials. If you decide not to consent into these trials, we would hope to be able to use the results from your specific tests from the central laboratory for other research. However, you can ask for the results not be given to anyone else or used in any way.

Local Contact names and telephone numbers:

Local Investigator: Dr ……
Telephone no: ……
Research Nurse:……
Telephone no: ……..

8 Flow chart for FOCUS4