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ARCTIC Trial

Attenuated dose Rituximab with ChemoTherapy In CLL:

A randomised, phase IIB trial in previously untreated patients with Chronic Lymphocytic Leukaemia (CLL) to compare fludarabine, cyclophosphamide and rituximab (FCR) with FC, mitoxantrone and low dose rituximab (FCM-miniR)

PATIENT INFORMATION SHEET AND INFORMED CONSENT DOCUMENT

A large-print version of this sheet is available on request.

You have been invited to take part in a research study called "ARCTIC". Before you decide whether to accept, we would like to explain why the research is being done and what it will involve. Please read this information carefully, and discuss it with others if you wish. Ask us if anything is unclear, or if you would like more information.

Take time to decide whether or not you wish to take part.

Thank you for reading this information sheet.

Part 1

What is the purpose of the study?

You are invited to take part in a research study known as a clinical trial. The study is looking at two combinations of drugs, one called fludarabine, cyclophosphamide and rituximab (FCR for short) and one called fludarabine, cyclophosphamide, mitoxantrone and reduced dose rituximab (FCM-miniR for short). This is a variation on established treatments and we wish to find out if they will be effective in treating patients with chronic lymphocytic leukaemia (CLL) who have not yet received any treatment for their disease and whether or not they cause a better response than other treatments.

A total of 206 patients with CLL will be invited to take part in this study. Half of the patients will be randomly selected (by computer) to receive FCR and the other half will be randomly selected to receive FCM-miniR. You will receive up to 6 cycles of treatment, with each cycle being given every 4 weeks and this is the same for all patients. This means that the total duration of your treatment will be approximately 24 weeks (6 months).

This study is being carried out at approximately 20 hospitals in the UK. It is expected that the study will take approximately 1.5 years to complete.

Why have I been chosen?

You have been invited to participate because you have been diagnosed with CLL which now requires treatment and your doctor believes that treatment with either FCR or FCM-miniR is appropriate at this time.

Do I have to take part?

No, ARCTIC is entirely voluntary. If you decide to take part you will be given this information sheet to keep. You will be asked to sign a consent form, but you are still free to withdraw at any time and without giving a reason. If you decide not to take part, your specialist will be happy to talk through alternative options with you and your treatment and care will not be affected in any way.

What will happen to me if I take part?

The best way of finding out whether one treatment is as effective as another treatment is in a randomised study. ‘Randomised’ means that a computer will allocate you randomly (as if by the roll of dice) to receive either FCR or FCM-miniR. Neither your doctor nor you will choose which treatment you receive. In this way, a fair comparison can be made.

Before going onto the study you will have a number of blood tests, a heart trace (ECG) and a CT scan (a type of X-ray). You will be examined thoroughly by your study doctor. If you are a woman, and capable of having children, a pregnancy test will be done before starting treatment to make sure you are not pregnant. This is to make sure that it is safe for you to receive the drugs in the trial. Only after we have completed all these tests will we be able to confirm that you may go ahead with the study.

Your treatment will be similar to the treatments usually used in CLL. You will receive up to a total of 6 cycles of treatment. Each cycle lasts 5 days and will be repeated every 4 weeks. You will be required to attend the day unit/ward in your hospital on the first day of each cycle of treatment to receive intravenous chemotherapy and the first day of your oral chemotherapy. The remaining 4 days of your oral chemotherapy will be taken at home.

During the study we will also need to take some blood and bone marrow samples at some of your routine visits to the hospital. Most of the blood tests and other investigations, such as bone marrow tests or CT-scans, are routine and would be performed to assess the safety of and response to your treatment whether or not you are taking part in the study; however, you should be aware that the bone marrow test may cause you some discomfort. At the initial visit, prior to commencing the first cycle of therapy, some extra tubes of blood (4 to 10 teaspoonfuls) will be taken to study your CLL in more detail, but this will not require an extra needle puncture. This is part of the study that we hope will allow us to identify which patients will respond the best to the treatments. Similar tests will be performed on samples of your bone marrow taken prior to the first cycle of therapy. In addition, a blood sample will be taken after your third cycle of treatment and blood and bone marrow samples will be taken 3 months after your final cycle of treatment to assess the response of your disease to the treatment. A CT scan will also be performed at this time. You should be aware that by receiving a CT scan you will be exposed to additional radiation although the health risks associated with this are low and are considered to be justified.

We will follow your progress for 2 years and this will involve at least 3 visits after the end of your therapy, usually on a 6 monthly basis. Depending on the results of the previous tests, we may need to take additional blood samples at these visits. If your doctor feels that it is appropriate, and depending upon the response of your disease, you may also need to have another CT scan at these time points. Once you have reached the 2 year post randomisation time point we would then like to follow you annually for the rest of your life in order to assess your long term progress after taking part in the trial.

The study also involves a health economics assessment which will help to find out the costs of the different approaches to treatment. This will involve you completing a questionnaire which

will ask you questions about your health and wellbeing and any health care services you have used. You will be asked to complete this questionnaire during your clinic visits at regular time points during the study.

If you are unable to travel to the hospital at any time during the study you should contact your haematology unit. If you need to see your own GP during the course of the study then he or she will already have been informed of your participation in the study.

What is the standard treatment?

The standard treatment for many patients with CLL who have not received any previous treatment in the United Kingdom is fludarabine, cyclophosphamide and rituximab (FCR).

What are the new treatments?

It is believed that adding mitoxantrone to FCR (FCM-R) may result in an improvement in response rates and that using a reduced dose of rituximab (miniR) may be just as effective as using the full dose. This study will therefore test whether FCM-miniR is as effective as FCR at improving response rates for previously untreated patients with CLL.

How long does treatment go on?

You will receive 6 cycles of treatment with either FCR or FCM-miniR. Each cycle is repeated every 28 days meaning that you can expect to receive treatment for approximately 6 months. If you experience any side effects it may be the case that your doctor wishes to delay some or all of your treatment cycles; side effects, which are common to all chemotherapy treatments, are further discussed later in this information sheet.

Your doctor will assess your progress after you have received 3 cycles of treatment and will make the decision for you to receive the next three cycles. If you are unable to tolerate treatment with FCR or FCM-miniR or are not responding to treatment your doctor may decide to stop your treatment before you have received 6 cycles.

What if the treatment doesn't help?

If your CLL levels start to increase then your doctor may decide to offer you a different treatment; details of this will be discussed with you at that time.

Unwanted effects of treatment

It is important to remember that all drugs have side effects. All chemotherapy can cause nausea, though this is usually well controlled with anti-sickness tablets. Chemotherapy for CLL with FCR and FCM-miniR is frequently associated with effects on the bone marrow. This can show itself in any of the following ways:

- Lower white blood cells which can increase the risk of infection.
- Lower red blood cells (called anaemia) which may give you shortness of breath, weakness and fatigue.
- Lower platelets (blood cells which make your blood clot) which may cause easy bruising or bleeding

In addition the following side effects may also occur:

Fludarabine has very commonly (that is, in over 10% of patients), been associated with increased coughing, vomiting, diarrhoea, fever; feeling tired, weakness, bruising, bleeding and infections (some serious) including infections of the lungs (*pneumonia*) with possible symptoms such as breathing difficulties. Fludarabine has commonly (that is around 10% of patients) been associated pins and needles, disturbed vision, mouth ulcers / sore mouth, skin rash, swelling due to increased fluid retention, chills and loss of appetite leading to weight loss. Cyclophosphamide has commonly (that is, around 10% of patients) been associated with irregular or absent menstrual periods in women, blood in the urine, hair loss (generally reversible), mouth ulcers / sore mouth, abnormal colouring of the skin usually affecting the palms of the hands, soles of the feet or nails, changes to the way food and drink tastes and loss of appetite leading to weight loss.

Cyclophosphamide may reduce the level of normal blood cells and make you more likely to get infections, anaemia or to excessive bleeding. These are monitored by blood tests but if they occur unexpectedly you should contact the hospital immediately. Rarely (less than 5% of patients) patients may become anaemic enough to need a blood transfusion.

Mitoxantrone has commonly (that is, around 10% of patients) been associated with pins and needles, confusion, sleepiness, anxiety, abnormal colouring of the skin usually affecting the palms of the hands, soles of the feet or nails, loosening of nails, sore mouth, skin rash, conjunctivitis (inflammation of the eye), constipation, black stools or blood in your urine or stools, stomach pain, changes to the way food and drink tastes and loss of appetite leading to weight loss

Mitoxantrone has rarely (that is less 5% of patients) been associated with blue/green discolouration to whites of the eyes or urine, hair loss, damage to the muscles of the heart, which may change the rhythm of the heartbeat, but it is unlikely to cause a problem in this study as the total dose of mitoxantrone is smaller than that likely to cause heart problems. Your heart will be monitored before you start the treatment to make sure that you are not at risk of these side effects.

Rituximab infusion can often cause mild and temporary side effects occurring mainly during the first infusion: fever, chills, headache, generally feeling unwell, tiredness, itching, redness of the skin, nausea and a mild drop in blood pressure. Most of these side effects disappear

upon temporary slowing or discontinuation of the infusion, or administration of paracetamol and/or anti-allergic medication. Less than 10% of patients have suffered from severe side effects with the first dose of rituximab including shortness of breath, dizziness and a fall in blood pressure. This has proved fatal in a very small number of cases. You will be monitored very carefully during and after the first dose to ensure that the rituximab may be stopped and appropriate treatment given if such side effects occur. Rituximab is given as a day case by a slow infusion to reduce the risk of reactions. If you are receiving FCR in the trial then the rituximab infusion will take 5 to 6 hours on the first dose and then slightly less on the subsequent courses of treatment. Since a lower dose of rituximab is given in the FCM-miniR patients then the initial infusion should take about 90 minutes and subsequent infusions should be completed in about an hour. Treatment with rituximab has also been associated with an increased risk of developing a viral or bacterial infection. In most cases these infections can be treated very easily but very rarely (that is less than 1% of patients) these may become serious and have occasionally proven fatal.

If you do decide to take part in the study, you must report any problems you have to your study nurse or doctor. There is also a contact number given at the end of this information sheet for you to phone if you become worried at any time. In the unlikely event of an emergency occurring during the conduct of the study, we may contact your nominated next of kin.

Do I need to make any lifestyle changes?

Your body's ability to fight infections will be lowered while you are on the treatment and for a few months afterwards. There is a slightly increased risk of getting rare and unusual infections while your immunity is lowered. During that period it is advisable to avoid contact with people who have sore throats, colds, flu, diarrhoea and vomiting, or other kinds of infection, such as chickenpox.

If you have pets or work with animals you will need to be extra careful. It is usually safe to pet or stroke animals as long as you wash your hands thoroughly afterwards. It is best to avoid handling any animal waste, such as litter trays or manure, as this can increase your chances of getting an infection.

It is important to avoid places and activities which make you more vulnerable to get infection with fungus like aspergillus. This can grow in dead leaves, grain stores, compost piles or other decaying vegetation. Brick, mortar and cement dust may also contain this fungus. It is preferable to avoid gardening activities like mowing the lawn. Wash your hands well after gardening and other outdoor activities

It is better to avoid any vaccination while you are on the treatment as some of the vaccinations can be harmful and most of them will not mount an adequate immune response while you are on the treatment.

It is preferable to avoid going abroad due to various reasons like accessibility to healthcare services, the drugs used and their complications may be unfamiliar in certain areas and vaccination if needed.

While you are on the treatment a 'clean' diet is recommended. This means avoiding certain food items like raw or lightly cooked eggs, shellfish, liver pâté, soft cheeses, takeaway food, uncooked salads. All food should be cooked thoroughly and stored in recommended temperature and use by date. It is still important to eat fruits and vegetables and it is recommended to eat those fruits and vegetables which are peelable.

Pregnancy during treatment, information for women and / or men

The effects of the drugs in both arms of the study on the unborn child are unknown. You cannot take part in the study if you are pregnant or breast feeding.

If, as a woman, you are able to become pregnant you **must** use a medically approved form of contraception; an intra-uterine device ('coil'), the contraceptive pill or injection and condoms are considered medically approved forms of contraception. You **must** continue to use a medically approved form of contraception whilst receiving any of the study drugs and for twelve months after you finish your last treatment cycle. Talk to your doctor if you are unsure about any other forms of contraception you may be using.

If, as a man, you are engaging in heterosexual activity with a woman who is able to become pregnant, you **must** use a medically approved form of contraception. You **must** continue using a medically approved form of contraception whilst receiving any of the study drugs and for twelve months after you finish your last treatment cycle.

If you are female and become unexpectedly pregnant you **must** inform your doctor immediately and you will be withdrawn from the study treatment. Other treatment options will be discussed with you at that time. If you are a male and your partner becomes unexpectedly pregnant you **must** also inform your doctor immediately so that your partner's pregnancy can be monitored.

How is my condition monitored?

Your progress will be monitored carefully. Your doctor will perform an examination before you start treatment and then after you have received 3 cycles of treatment. If your doctor is happy that you are tolerating the treatment he/she will then decide that you can receive the next 3 cycles of treatment. If you are not tolerating treatment your doctor may decide that you need to stop receiving further treatment. Your doctor will then assess you at the end of treatment and also 3 months after treatment and then 12 months, 18 months and 24 months after you first agreed to take part in the study. Further long term follow up will be discussed by your doctor at the time.

As already mentioned you may experience side effects which should be reported to your doctor at each visit.

Please tell us about any problems, as we can often help.

What are the possible disadvantages and risks of taking part?

As already discussed you may experience side effects following treatment with any of the study drugs. You will be monitored regularly whilst receiving study treatment. You will be examined by the study doctors and blood tests will be taken to check for side effects. If you suffer any side effects which you think may be related to the study, please inform the study nurse or doctor as soon as possible.

The effectiveness of the treatments may be different in certain individuals and therefore may have no direct benefit to your disease.

Taking bone marrow samples may cause you some pain or discomfort. If you decide to participate in the study a bone marrow sample will be collected before you receive treatment and 3 months after your treatment has ended. However, you should be aware that a bone marrow sample would also be collected at these time points as part of your standard care if you decide not to participate in the study.

The number of blood samples taken as part of the study is also the same as that taken as part of your routine care.

The additional CT scans will give a radiation dose equivalent to that received from normal background radiation over approximately 15 years. This carries a very small increase in your risk of developing cancer in later years (with a risk of about 1 in 400 of fatal cancer), but a Clinical Radiation Expert has certified that the exposures are justified by the potential benefits of the new treatment to yourself and to future patients.

Being involved in a research study such as a clinical trial involves a degree of commitment such as regular hospital visits and additional tests, as described above. It is not expected that you will need to stay in hospital over night but occasionally this may be necessary to treat any side effects.

What are the possible benefits of taking part?

If you agree to take part in this study, there may or may not be direct medical benefit to you. We hope that the treatments will help you, but the effectiveness of the treatments may be different in certain individuals and therefore this cannot be guaranteed. The addition of rituximab to chemotherapy appears to add to the effectiveness of treatment in CLL and all patients within this study will receive rituximab as part of their treatment. It is believed that low dose rituximab may be just as effective as full dose rituximab and that it may have fewer side effects than full dose rituximab, but the trial will need to show this. Research studies such as clinical trials are essential for progress in the development of treatments for diseases. Although we cannot guarantee that the treatments will be beneficial to you, the results

obtained from this study will also provide important information which may help people with CLL in the future. Without research such as this, no improvement is possible.

What if something goes wrong?

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms should be available to you. Your doctor will give you further information, if necessary.

What happens when the research study stops?

Should you require further treatment for your disease after you have finished treatment in this study, further treatment options will be discussed with you by your doctor. Whether further treatment is required or not, you will continue to be reviewed on a regular basis as part of the study. We will follow your progress for 2 years after you have finished trial treatment and this will involve at least 3 visits after the end of your therapy, usually on a 6 monthly basis. Once you have reached the 2 year post randomisation time point we would then like to follow you annually for the rest of your life in order to assess your long term progress after taking part in the study.

Additional research

There is also the opportunity to take part in an additional research project called the UK CLL Trials BioBank. This project involves having additional blood samples and a saliva sample taken before you start treatment. If your doctor is able to extract enough bone marrow when a sample is taken before you start treatment and 3 months after treatment has ended, part of the sample will also be sent to the UK CLL Trials BioBank. Another blood sample will also be taken if your disease re-occurs. The samples will be sent to and stored by the UK CLL Trials BioBank at the Royal Liverpool University Hospital, and they will then be will be analysed for things that might be of value in predicting how well individual patients respond to treatment and shed light on possible new treatments. If you wish to take part in the UK CLL Trials BioBank your doctor will provide you with a separate consent form and patient information sheet which are specific to this project. Participation in the additional research is entirely optional, and your decision to participate will not affect your participation in the rest of the study.

Will my taking part be kept confidential?

If you consent to take part in this study, the records obtained while you are taking part as well as related health records will remain strictly confidential at all times. Please refer to Part 2 of this information sheet which provides further details of confidentiality.

Contact Details

If you have any further questions about your disease or clinical studies, please discuss them with your doctor. You may also find it helpful to contact Cancerbackup, an independent cancer information charity (freephone: [redacted]; address: [redacted]; website www.cancerbackup.org.uk) or CancerHelp, an information service about cancer and cancer care for people with cancer and their families by Cancer Research UK (Tel: [redacted]; website www.cancerhelp.org.uk). If you would like further information about clinical research, the UK Clinical Research Collaboration (a partnership of organisations working together on clinical research in the UK) has published a booklet titled 'Understanding Clinical Trials'. Contact UKCRC: Tel: [redacted]; website www.ukcrc.org

Your contact telephone numbers:

……..

……..

This completes Part 1 of the Information Sheet. If the Information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

Part 2

What if relevant new information becomes available?

Sometimes during the course of a clinical trial or study, new information becomes available or the drugs that are being studied. If this happens, we will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, we will make arrangements for your care to continue. If you decide to continue in the study, you may be asked to sign an updated consent form.

On receiving new information, we might consider it to be in your best interests to withdraw you from the study. If so, we will explain the reasons and arrange for your care to continue.

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

If you withdraw consent from further study treatment, your data and samples will remain on file and will be included in the final study analysis. In line with Good Clinical Practice guidelines, at

the end of the study, your data will be securely archived for a minimum of 15 years. Arrangements for confidential destruction will then be made.

Who has organised, reviewed and funded the research and who will be supervising it?

The study is being organised by the University of Leeds, who will collect and analyse your data. The study was reviewed and approved by the National Cancer Research Institute CLL Sub-Group Committee, the Leeds East Research Ethics Committee and the Local Research Ethics Committee situated at your hospital.

The study is being funded by the Health Technology Assessment Programme (HTA) which is part of the National Institute for Health Research (NIHR). Part of the funds will be used by the University of Leeds who are organising the study and collecting and analysing your data. Part of the funds will also be used by the Haematological Malignancy Diagnostic Service (HMDS) at St. James's University Hospital who will study the blood and bone marrow samples which you have given.

What if there is a problem?

If a medical emergency related to your treatment for this study occurs while you are at home, you should initially try to contact the haematology unit where you received your treatment <<contact details will be added>>. If this is not possible you should go to the Accident and Emergency (A&E) department at your local hospital. If you are unable to get to the hospital you should contact your GP who, with your consent, will already have been informed of your participation in the study.

Complaints:

If you wish to complain, or have concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms should be available to you.

Harm:

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action but you may have to pay for it.

Will my taking part in this study be kept confidential?

If you decide to participate in ARCTIC, the information collected about you during the course of the study will be kept strictly confidential. This information will be securely stored, on paper and electronically, at the Clinical Trials Research Unit (CTRU) at the University of Leeds

under the provisions of the 1998 Data Protection Act. The CTRU will hold a copy of the consent form that you sign, which will have your name on it. This information will not be accessed by any other personnel. In addition some of the study information collected, for example the Health Economics Patient Questionnaire Booklets, will be securely stored on paper and electronically at the Academic Unit of Health Economics at the University of Leeds; this information will only be accessible by a member of the research team.

Every effort will be made to ensure that any further information about you that leaves the hospital will have your name and address removed so that you cannot be recognised from it. This information will usually be removed by a member of the study team at your hospital, but may also be removed by the CTRU upon receipt. You will be allocated a study number, which will be used as a code to identify you on all study forms. Only the CTRU and your hospital will be able to identify you from this number.

With your permission, the CTRU may register your details (which will include your full name, date of birth, NHS number and last known address) with the Office of National Statistics, so that if you move away we will be able to find out how you are doing.

With your permission, your relevant medical records may be inspected by authorised individuals from the research team or the University of Leeds (the study Sponsor). They may also be looked at by the regulatory authorities to check that the study is being carried out correctly. In addition, some of your data may be passed to other organisations (possibly in other countries where the data protection standards and laws are different from the UK) to monitor the safety of the treatment(s) that you are receiving. This data will have your name removed so that you cannot be identified from the information.

When the study is complete the results will be published in a medical journal, but no individual patients will be identified. If you would like to obtain a copy of the published results, please ask your doctor.

Involvement of the General Practitioner/Family Doctor (GP):

Your GP, and the other doctors involved in your clinical care, will be notified and kept informed of your participation in ARCTIC, but otherwise all information about you and your treatment will remain confidential.

What will happen to any samples I give?

Researchers at the central laboratories at the Leeds Teaching Hospitals NHS Trust will have access to your blood and bone marrow. The researchers will use the samples to look at a variety of factors in your CLL cells. These factors might have a positive or negative impact on the probability of your CLL responding to treatment. This information will help to identify which factors are important and will help our treatment of future patients with CLL. Although these samples will be analysed for this study, (i.e. research) some of the results may be useful to your doctor for your clinical management.

The samples will therefore be labelled according to NHS standard practice and will not be made anonymous, so that the results can be fed back to your study doctor. The laboratories will handle your samples with the same duty of confidentiality as they would for any clinical sample. They will be retained at the end of the study as a record of the completed research study in order to verify the research results, if required.

If any information from this study is used to develop new research, data protection regulations will be observed and strict confidentiality maintained; your data will have your personal details removed, but will be coded so it can be linked back to your details. You will not be identified in the results of future studies. Ethical approval will be obtained for any future studies involving your data or samples.

There is also the opportunity to take part in an additional research project called the UK CLL Trials BioBank. As previously discussed, this project involves having additional blood samples taken along with a saliva sample before you start treatment. If your doctor is able to extract enough bone marrow when a sample is taken, before you start treatment and 3 months after treatment has ended, part of the sample will also be sent to the UK CLL Trials BioBank. In addition, if and when your CLL progresses after therapy then a further blood sample will be taken for the UK CLL Trials BioBank to help investigate why the CLL has returned. The samples will be sent to and stored by the UK CLL Trials BioBank at the Royal Liverpool University Hospital, and they will be analysed for things that might be of value in predicting how well individual patients respond to treatment and shed light on possible new treatments. If you wish to take part in the UK CLL Trials BioBank your doctor will provide you with a separate consent form and patient information sheet which are specific to this project.

Your samples will **not** be used for commercial purposes.

Will any genetic tests be done?

If you decide to take part in the additional UK CLL Trials BioBank project then genetic tests may be performed on your samples.

Certain genetic changes in the CLL cells are important for the development of CLL and also for the likelihood of individual patients responding to treatment. These genetic changes will be analysed in your CLL. In addition it is likely that certain genes may increase the likelihood that an individual will develop CLL and increasing numbers of genes and combinations of certain genes are being identified. These current and new genetic changes will be studied in the samples taken from this study. This work is important to understand that leukaemia develops and progresses because something goes wrong with one or more genes. In order to understand more about CLL and improve its treatment it is therefore necessary to examine leukaemia cells for genetic abnormalities.

In addition, many normal genes can exist in slightly different forms called “polymorphisms”; this is what makes each human being unique. It is important to study gene polymorphisms in CLL as doing so could shed light on why the disease affects some people but not others, why

it behaves differently in different patients, and why treatments work better in some patients than others.

What will happen to the results of the research study?

The results of the study will be available after it finishes and will usually be published in a medical journal and also on the CancerHelp website. Should you wish to see the results, or the publication, please ask your study doctor. You will not be identified in any report or publication.

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Patient ID:	Initials:
Date of Birth:	Hospital Number:
EudraCT Number:	Version:
Principal Investigator:	

ARCTIC

Attenuated dose Rituximab with ChemoTherapy In CLL:

A randomised, phase IIB trial in previously untreated patients with Chronic Lymphocytic Leukaemia (CLL) to compare fludarabine, cyclophosphamide and rituximab (FCR) with FC, mitoxantrone and low dose rituximab (FCM-miniR)

PATIENT CONSENT FORM

	Patient initial after each question
1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions.	.....
2. I understand that my participation is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected.	.....
3. I understand that my medical records may be looked at by authorised individuals from the research team, regulatory bodies or Sponsor in order to check that the study is being carried out correctly. I give permission, provided that strict confidentiality is maintained, for these bodies to have access to my medical records for the above study and any further research that may be conducted in relation to it.	.....
4. I understand that even if I withdraw from the above study, the data and samples collected from me will be used in analysing the results of the trial, unless I specifically withdraw consent for this. I understand that my identity will remain anonymous outside of the NHS.	.....
5. I agree to allow any information or results arising from this study to be used for healthcare and/or medical research purposes including monitoring the safety of the treatment that I will receive. I understand that my identity will remain anonymous outside of the NHS.	.....
6. I agree for my details (which will include my name, date of birth, NHS number and address) to be registered with the Office of National Statistics (ONS) or traced via the NHS Strategic Tracing Service so that information about my health status may be obtained by the CTRU if necessary.	.....
7. I understand that a copy of this Consent Form will be sent to the CTRU	.....

8. I agree that my GP, or any other doctor treating me, will be notified of my participation in this study. .....

9. I agree to take part in the study .....

The following points are OPTIONAL.

Even if you agree to take part in this study, you do not have to agree to this section

	Please initial after each question	
	Yes	No
10. I give permission for surplus specimens from my leukaemia that have been stored in the hospital pathology laboratory to be retrieved and used in the future for CLL cancer research.	☐	☐

Name of patient	Date	Signature
Name of Person taking consent	Date	Signature

(1 copy for patient; 1 for the CTRU; Original stored in Investigator Site File)