Delete this line, then print on Trust/Hospital headed paper

Personalising treatment for myeloma patients based on how well they by initially respond to a period of NHS treatment and their overall fitness level

Additional information

You don't have to read any of this information before making your decision about taking part, if you don't want to. But it may provide answers to any questions you have now or in the future.

Summary of information about the research

To help you understand the research, the information if split into several documents:

iFIT document	This document	When will I receive this?	What is being asked of me?
Bone marrow sharing		When having tests to find out if you have myeloma	Do you agree to share a sample of your bone marrow from your planned tests?
Study registration		If you are diagnosed with myeloma	Do you agree to be monitored whilst having the NHS treatment DRd, and for us to collect your data and samples?
Randomised study treatment		After completing a period of the NHS treatment DRd	Do you agree to continue to take part in the research and be randomly allocated to a further treatment based on your data?
Additional information [optional - you don't have to read this before you make your decision]	✓	At the same time as the 'Study registration' document above	Nothing is being asked of you here. This is additional information you may find interesting or helpful.

Large-print and electronic versions of all documents are available. Visit https://ctru.leeds.ac.uk/ifit.

More about the research

What does iFIT stand for?

iFIT (pronounced “i-FIT”) stands for ‘**I**mmunotherapy approaches adapted for **Fit**ness in newly diagnosed transplant ineligible patients with Myeloma’.

How can you tell how well I respond to the NHS treatment DRd?

At the end of the period of DRd treatment, we will collect a sample of your bone marrow aspirate (fluid). Ask your hospital doctor if you have any questions about this process.

This sample will be sent to the iFIT laboratory (the Haematological Malignancy Diagnostic Service (HMDS) in Leeds) for testing. The result of the test will either be MRD positive (‘MRD+’) or MRD negative (‘MRD-’). MRD stands for measurable residual disease, i.e., how much myeloma is detected in your bone marrow.

If you are MRD+, this means you have current detectable myeloma cells in your bone marrow, so the disease remains present.

If you are MRD-, this means you do not currently have detectable myeloma cells in your bone marrow, so the disease is currently in a very deep response.

You might have a type of myeloma which cannot be measured in this way. If this is the case, your hospital doctor will discuss this with you. You may still be able to take part in the research as MRD positive (‘MRD+’).

How can you determine my level of fitness?

We will use a well-tested process to assess your level of fitness, in other words, how frail you are. The process is the ‘International Myeloma Working Group (IMWG) frailty score’. The score considers your age, other illnesses, and whether you can live independently. It includes three groups: fit, unfit, and frail. You will be put into a group that best matches your level of fitness.

Who is included in the further treatment options in terms of MRD and frailty?

If you are fit or unfit, and MRD+ you could receive one of the following further treatments:

- Continuing the NHS treatment DRd as long as your myeloma remains under control, or
- Daratumumab plus one of two new immunotherapy treatment (teclistamab or talquetamab) for 18 28-day cycles. Immunotherapy treatments help your own immune system fight diseases.

If you are frail and MRD+ you could receive one of the following further treatments:

- Continuing the NHS treatment DRd as long as your myeloma remains under control, or
- Continuing daratumumab and lenalidomide treatments as long as your myeloma remains under control.

If you are fit, unfit, or frail, and MRD- you could receive one of the following further treatments. The treatment will be based on there being no current detectable myeloma cells, regardless of fitness:

- Continuing daratumumab and lenalidomide treatments as long as your myeloma remains under control, or
- Continuing daratumumab and lenalidomide treatments for 18 28-day cycles.

What if my myeloma progresses (gets worse) during this research?

If your myeloma progresses (gets worse) during this research, your hospital doctor will discuss your treatment options with you. This could happen at any time during the first 6 cycles of the NHS treatment DRd or during any of the further treatments.

We will continue to collect data about you to see how you are doing. We will also still ask you to complete questionnaires, unless you tell us you want to stop.

Who are the research team?

Professor Gordon Cook,
Professor of Haematology

Dr Charlotte Pawlyn,
Consultant Haematologist

They are interested in how myeloma develops and can be treated. They both also lead key work in laboratories. They have designed and led several national myeloma trials, and sit on multiple national and international committees.

https://medicinehealth.leeds.ac.uk/medicine/staff/1414/professor-gordon-cook

https://www.icr.ac.uk/research-and-discoveries/find-a-researcher/test-researcher-profile-detail/dr-charlotte-pawlyn

The Clinical Trials Research Unit at the University of Leeds

We are the central co-ordinating team working with Professor Cook and Dr Pawlyn, as well as other investigators and people with myeloma, to implement and deliver iFIT. We manage the research and analyse the data.

On a day-to-day basis, this includes ensuring that:

- Participants stay safe,
- The research is delivered in accordance with ethical and regulatory regulations,
- Participants receive their study treatment, and
- High-quality data is recorded to answer the research questions.

We monitor how the research is going against key criteria and try to ensure the research is delivered to time, target, and within budget.

Through our research, we are passionate about improving the quality of the lives of people with myeloma. We are excited to be involved in iFIT as it will answer important questions that has the potential to change clinical practice.

How do the immunotherapy treatments (teclistamab and talquetamab) work?

These treatments are bispecific antibodies. This means they target both the myeloma cells and one of the immune cells called a “T cell”. The drugs act like a magnet attaching to proteins on both:

- the surface of the myeloma cells, and
- the surface of the T cell.

It brings those two cell types close together. This leads to the immune system targeting the myeloma cells for destruction. The difference between teclistamab and talquetamab is that they target different proteins on the myeloma cell.

Who will benefit from the results of the research?

We hope this research will be of benefit to myeloma patients in the future by answering important questions about myeloma care. Our aim as a team is to improve treatments for patients in the NHS. We can’t guarantee that this research will change clinical practice in the NHS, but we’ll do our best if the results of the research are positive.

Taking part in this research may also contribute to drugs being available commercially. Johnson & Johnson Innovative Medicine, or others, may benefit from this financially. Participants taking

part in this research will not receive payment nor have rights to any patents or discoveries arising from this research.

How is the research reviewed, approved, and monitored?

Have patients and members of the public been involved in the research?

A group of people with myeloma helped in the design of the research. They have also been involved in, and will continue to be involved in, information produced for the research. This includes the information sheets like this one.

What is the role of the Research Ethics Committee (REC)?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee (REC). This is to protect your safety, rights, wellbeing, and dignity. This research has been reviewed and given a favourable opinion (approval to start the research) by South Central - Oxford C Research Ethics Committee (25/SC/0279).

What is the role of the Medicine and Health Research Authority (MHRA)?

All research is also reviewed by the Medicine and Health Research Authority (MHRA) to ensure the medicines are being used safely. This research has been reviewed and been given approval by the MHRA (16767/0317/001-0001).

What are the roles of the Data Monitoring and Ethics Committee (DMEC) and Trial Steering Committee (TSC)?

Throughout the research, independent groups of people such as doctors, statisticians, and trial experts, will meet. They will meet at least once a year to review the progress of the research and the data collected so far. This is to see how well it is going and that it is safe for participants. They can advise that the research stops if they find that it is no longer safe, or that one of the treatments is clearly better. These groups are known as the Data Monitoring and Ethics Committee and Trial Steering Committee.

Guide to completing questionnaires online

You may choose to complete questionnaires online when you start to receive further treatment, if you wish to, or you may continue to complete them on paper. The first two questionnaires you complete during the first 6 cycles of the NHS treatment DRd will always be on paper.

The below information is for if you wish to complete questionnaires online when you start to receive further treatment.

What system do you use?

The questionnaires you complete will be on a web application called Research Electronic Data Capture (REDCap). REDCap is a secure application.

How can I access REDCap?

You can access REDCap on a smart phone, tablet, or a computer.

How do I use REDCap?

You will be asked whether you would like to be sent the questionnaires by text, email, or both.

Step 1: Click on the link sent to your phone and/or email. You will be directed to the online questionnaires.

Step 2: Click the 'Begin Survey' button to open the questionnaire.

Step 3: Answer each question, clicking 'Next page' or 'Submit'. Each time you click 'Submit' the questionnaire will be saved and you will be taken back to the link page to complete the next questionnaire.

Step 4: Repeat these steps until all questionnaires are complete.

Do I have to complete the questionnaires in one go?

No, if you would like to finish the questionnaire at a later time, you can click 'Save & return later'. To do this, make sure you write down the return code, and either bookmark the page or write in your email address to receive another link.

Can I change my mind?

If you choose to complete questionnaires online and find it doesn't work for you, let your hospital doctor or nurse know.

Stopping or changing your level of participation

Can I stop taking part in some parts of the research while still carrying on with others?

Yes. For example, you might stop completing questionnaires but keep going to research visits. Or you might stop research visits but still allow information about you to be collected from any routine health visits you make.

It helps the research for you to continue making some sort of contribution for as long as you can. The more of the planned information we collect for the research, the more reliable the research results can be.

Can I keep taking the study treatments but stop all other parts of the research?

Treatment with daratumumab, lenalidomide and dexamethasone (DRd) is available on the NHS, so you can decide to completely stop taking part in the research while still having the treatment.

It is helpful in research to collect as much of the planned information as possible. If you want to stop giving your time to take part in the research, you might be able to still contribute but with much less of your time. For example, if you are still OK for information to be collected from your routine appointments then you could still help the research but without so much commitment. Contact your hospital doctor or nurse to discuss what might be possible.

If you take part in this research, we will need to keep collecting some information about serious side-effects you experience at any time until the end of the research. See “Why does information about side-effects still need to be collected?” below.

Some of the further treatments (teclistamab and talquetamab) are not currently available outside of this research. This means you can only keep getting them while you are taking part in the research.

This is important for your safety. We are doing the research to learn more about the safety of teclistamab and talquetamab treatments. We need to keep monitoring the safety of all the research participants during the research. If someone stopped taking part but kept taking these treatments, we wouldn’t be able to monitor their health in the same way, and so it wouldn’t be safe for them or future patients.

What should I expect to happen if I say I want to stop taking part?

It can be helpful for you and for the research if you can discuss your involvement with your hospital doctor or nurse. They can explain what your options are, and you can tell them exactly what you want to do.

Your hospital doctor or nurse may be able to help with the things that are making you want to stop taking part. With their support, you may find that you can carry on in the research after all. But it's fine if you do want to stop. Your hospital doctor or nurse will confirm what will happen next.

You won't have to complete any forms or sign anything to stop taking part. Just saying what you want to do is enough.

Your hospital doctor or nurse will make clear what will happen next about your treatment and care. Ask for more information on this if you need to.

Feel free to ask if you need more support while you leave the research. It should be made clear who your main contact will be about your myeloma, especially if it won't be someone who works on the research.

If you agreed before for your GP to find out about you taking part in the research, your hospital doctor or nurse may inform your GP that you have stopped.

Your hospital doctor or nurse may ask you whether you want to get updates about the research in future. For example, you might want information about the research results at the end.

Your hospital doctor or nurse may ask you if you'd be willing to say why you want to stop taking part. It's fine if you would prefer not to say why. See below for more information: 'Why is it useful to know my reasons if I stop taking part?'.

You will receive a short information sheet. This will confirm how your involvement in the research has changed, what it means for you and what will happen next.

Why is it useful to know my reasons if I stop taking part?

You don't have to give any information about why you're stopping if you don't feel comfortable about saying.

However, it can be useful to know if you have any feedback on your experience in the research. This can help the research team improve patients' experiences in this research and improve how other research is planned and run in the future.

It can also be helpful if you are willing to give a reason why you want to stop taking part. This can help the research team understand the results of the research better.

Knowing people's reasons for stopping can help the research team understand if people who stopped taking part might have done better or less well (in terms of their health) than people who carried on in the research.

It is especially helpful to know if stopping has anything to do with changes in your health. We would not need to know any more detail than that for it to be useful information. Any information you give to us will be treated sensitively and confidentially.

Why can't my information be deleted if I stop taking part?

Usually, when an organisation has information about you, you can ask them to delete it, or only use it in certain ways. However, this does not apply to the information used for research like this. It would harm the quality of the research if people could remove their information. This is important because patients in future are affected by the results of research.

We also need to comply with rules about research that say we need to keep all the information for a while after the research finishes. This allows authorities who oversee research to check that the research has been carried out correctly. This is important because the results of research often impact on the treatment patients receive.

If you stop taking part, we will therefore keep the information we already have about you. We will still include it in the research results. We will make sure we keep information about you secure and confidential. No one will be able to see who you are from the research results.

Research done in the public interest has special protection under the General Data Protection Regulation (GDPR). You can read more about this on the Information Commissioner's Office website: https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/the-research-provisions/

Why does information about side-effects still need to be collected?

We will still need to collect some information about you, even if you tell us you do not want us to collect any more. We will need to know about any serious side-effects you have, or health events that happen that might be related to the treatment you have received in the research. This is a legal requirement in the UK.

It is important as it means that doctors using the same treatment in the future have all the information they need about any possible side-effects.

You won't need to do anything extra for this. If your hospital doctor finds out that you have experienced certain sorts of serious side-effects any time before the end of the research, then they would let us know.

They would send us a small amount of information. The information would be kept secure and wouldn't be given to anyone else in a way that could identify you.

Can I still stay in touch with the research if I stop taking part?

You can keep up to date with the research on our website: https://ctru.leeds.ac.uk/ifit.

What if something goes wrong?

How do I make a complaint?

Any complaint about the way you have been dealt with during the research or any possible harm you might suffer will be addressed. If you have a concern about any aspect of this research, you should speak to your hospital doctor or nurse at your hospital who will do their best to answer your questions.

If you remain unhappy and wish to complain formally, you can do this through the NHS complaints procedure. Details can be obtained from your hospital. Alternatively, you may contact your local Patient Advisory Liaison Office.

Any claims will be subject to UK law and must be brought in the UK.

Useful links

iFIT website: https://ctru.leeds.ac.uk/ifit. Here you can find out how the research is going, and you can also access electronic versions of all of the information sheets (see the summary on page 2).

Myeloma UK support: https://www.myeloma.org.uk/me-and-myeloma/i-am-newly-diagnosed/

You may also find it helpful to contact Macmillan Cancer Support, an independent cancer information charity (freephone: **0808 808 00 00**; address: 89 Albert Embankment, London, SE1 7UQ; website www.macmillan.org.uk) or get more information from the charity Cancer Research UK at https://www.cancerresearchuk.org/about-cancer.

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) have published various resources to help people learn more about research and clinical trials. Contact UKCRC: Tel: 0207 395 2271; email: info@ukcrc.org; website www.ukcrc.org.

iFIT record on the ISRCTN registry: https://www.isrctn.com/. This is a public record and is not necessarily aimed towards a patient population.

CRUK trials database: https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial

Getting involved in research: https://www.nihr.ac.uk/get-involved

The Medicines and Healthcare products Regulatory Agency (MHRA): https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about