# DOMINO DFU logo

# Diagnosis of OsteoMyelitis: INvestigation Optimisation in Diabetic Foot Ulcers

# PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT DOCUMENT: PHASE 1

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

You have been invited to take part in the DOMINO-DFU study which is looking at outcomes of patients with new diabetic foot ulcers (DFUs). Some people with new DFUs develop certain wound characteristics that suggest a higher risk of bone infection at the base of the wound (this is called osteomyelitis). This study is looking at different ways to identify bone infection at the base of the wound, and how this affects treatment and outcomes of the wound. Before you decide if you would like to take part we would like to explain why the research is being done, how we will use the information we have about you, and what the study will involve.

Please read this information carefully and discuss it with others if you like. Ask us if anything is unclear, or if you would like more information.

**Once you have read this information, a member of the research team will talk to you about the study again and you can ask any questions you like.**

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

**Further information**

If you have any questions about this study, please talk to;

<<Enter PI or research team contact name >>

<< Contact details for site>>

For any questions regarding your foot ulcer outside of normal hours please contact;

<<Enter out of hours contact details>>

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 a booklet entitled ‘Understanding Clinical Trials’. For a copy contact UKCRC: Tel 0207 670 5451 or visit their website [www.ukcrc.org](http://www.ukcrc.org). Further information about the DOMINO-DFU study is available at <https://ctru.leeds.ac.uk/domino-dfu> and <https://bepartofresearch.nihr.ac.uk/>

**Thank you for taking the time to read this information sheet.**

**PART 1 tells you the purpose of this project and what will happen to you if you take part.**

**PART 2 gives you more detailed information about the conduct of the study.**

**PART 3 will provide some extra information about data protection**

**PART 1**

**What is Osteomyelitis?**

* Diabetic foot ulcers are wounds on the feet that occur in people with diabetes, mainly due to nerve damage, causing areas of high pressure when you walk, and reduced feeling in the foot. Most wounds have bacteria on their surface, and if there are enough bacteria this can cause infection. This is why it is important to keep your wound clean and dry. Areas of high pressure usually occur over a bony prominence, and if the wound is deep, then the bone at the bottom of the wound can also become infected, a condition called osteomyelitis. Infection in the bone underlying a diabetic foot ulcer affects about 1 in 5 ulcers.
* Your Podiatrist and Consultant will monitor your wound for signs of infection such as redness, swelling and heat; or evidence of bone at the base of your ulcer. These are known as ‘high-risk clinical features’ for bone infection (osteomyelitis).
* Treatment for osteomyelitis is usually with a long course (typically 6 weeks) of antibiotics, but may require surgery to remove the infected bone which can lead to amputation of a toe or part of the foot.

**Summary - what do you need from me if I take part?**

* We would like your permission to access routine medical record data to collect information about your diabetic foot ulcer, and whether it has healed after 12, 24 and 52 weeks. If the data on wound healing we need for the study is not available from records at these time points we may ask to see you or call you to ask you about your wound and the treatment you have received. If you need to come to hospital for an extra visit we will be able to help with the cost of travel and parking.
* If you develop high-risk clinical features for bone infection:
  + We would like your permission to access more detailed medical record data to look at diagnosis, treatment and outcomes of any bone infection at 12, 24 and 52 weeks after you developed high-risk characteristics of bone infection. If the data we need for the study is not available from records at these time points we may ask to see you or call you to ask about your wound and the treatment you have received. If you need to come to hospital for an extra visit we will be able to help with the cost of travel and parking.
  + We will ask you to complete quality of life and health resource questionnaires at 0, 4, 8, 12, 24 and 52 weeks (paper or electronic versions). Completing the questionnaires will take 15-20 minutes each time. Completing questionnaires is optional and you can take part in the study without agreeing to complete questionnaires.
  + We plan to seek approval for the study to continue into Phase 2. If this is successful we may also ask for additional consent to take two bone biopsy samples (you would normally have 1 taken), but this would be optional. If you agree to this your appointment would take an extra 20 minutes to normal. Phase 2 of the study is not yet approved and we will provide more information about this if Phase 2 has been approved at the time you become high-risk

**What is the purpose of this study?**

The overall aim of the study is to;

* Recruit everyone with a new diabetic foot ulcer so we can see how common bone infection is amongst people with a diabetic foot ulcer.
* Try and improve the diagnosis of bone infection in people with diabetic foot ulcers who develop high-risk clinical features for bone infection.

There is no standard way to diagnose a bone infection, and at the moment doctors and podiatrists use different ways to decide on the diagnosis. There are risks associated with missing the diagnosis, and studies suggest that it may therefore be over-diagnosed leading to unnecessary prolonged antibiotic courses in some people.

For those with high-risk clinical features for bone infection, i.e. those appearances of the wound which may make your treating clinician consider a diagnosis of bone infection, we are looking to get additional information over 3 phases of the study:

1. How are clinicians currently making the diagnosis and what are the outcomes (recruiting for 6 months)?
2. Can we take a sample of bone in a different way to improve the diagnosis with fewer tests making an incorrect diagnosis (either wrongly making, or wrongly ruling out the diagnosis – recruiting for 18 months)?
3. Can we produce a set of diagnostic criteria using the clinical features and the tests recommended in guidelines (blood tests, X-rays and bone sample) that improves diagnosis and clinical outcomes for patients (18 months recruitment)?

We hope that the results of the study will help change future guidelines and improve care and outcomes of patients with diabetic foot ulcers.

**What phase of the study are we in?**

We are currently in PHASE 1 of the study.

In this Phase we are;

1. collecting information from ***all*** people who come to clinic with a new DFU
2. asking people who develop high-risk clinical features to collect additional data and complete questionnaires (completing questionnaires is optional)

This information will help us to understand how common bone infection is and how it is currently being diagnosed by Doctors and Podiatrists.

If may be that the high-risk part of the study has moved to PHASE 2 by the time you develop high-risk clinical features for bone infection. If this is the case, we will provide you with more detailed, ethically approved information at that time. This includes an extra bone biopsy sample, and therefore joining the high-risk group in phase 2 is optional and we would need further consent from you to go ahead at that time.

No, your participation in DOMINO-DFU is completely voluntary. If you decide not to take part, your treatment and care will not be affected in any way. If you do decide to take part you may withdraw your consent to take part at any time, without giving a reason

**Do I have to take part?**

**Why have I been invited?**

You have been invited because you have come to your diabetic foot clinic with a new ulcer.

We are asking anyone coming to the diabetic foot clinic with a new ulcer to take part in study. This will allow us to work out what proportion of all those with new foot ulcers develop high-risk clinical features for bone infection, and how many of these are treated for bone infection.

**Why am I being invited to take part?**

Treatment for a DFU includes regular attendance at the DFU clinic to check your wound, removal of hard skin (if needed), dressings, footwear to offload the pressure on the wound, and access to other assessments and treatments such as improving sugar levels and checking the blood supply to the foot.

DFUs which develop high-risk clinical features for bone infection may have swabs, tissue samples or bone samples taken, and antibiotics are given as per local hospital policy. You will also have blood tests taken and an x-ray of your foot and/or other scans

**What are the standard treatments and tests?**

All of the treatments and tests described above will continue as normal if you take part in the study. If you agree to an additional bone biopsy in Phase 2 (when this Phase has been approved to start), this will be in addition to the standard tests, using equipment provided by the study. There will be more information about this in a separate information sheet. Your care will not change by taking part in the study.

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**What will be done differently in this study?**

**What will happen to me if I decide to take part and do not develop high-risk clinical features for a bone infection?**

* Your care will continue as normal
* We would collect very limited data, usually from your medical records, at 12, 24 and 52 weeks after you join the study
* We may need to contact or see you at these follow-up time points to get information on your ulcer if we can’t get all of the information we need from your medical records. This will usually be at a routine clinic appointment, but may need to be an extra clinic visit or phone call to check whether your ulcers have healed or not.
* If you need to come for an extra clinic visit we can help with travel & parking costs.
* We will also continue to monitor any ulcers at any clinic visit until the end of the study to see if you have developed any features suggestive of bone infection, even if this is after 52 weeks from when you join the study. You may also be given the opportunity join another phase of the study after this 52 weeks. A separate, ethically approved information sheet would be provided at this point.

**What will happen to me if I decide to take part and develop high-risk clinical features for a bone infection?**

* Your care will continue as normal
* You will complete diagnostic tests which follow current standard practice at your hospital
* We will collect some more detailed information from your medical records at 0, 12, 24 and 52 weeks after you are identified as having high-risk clinical features for a bone infection including
  + what diagnostic tests have been done and the results,
  + the treatment you receive
  + the outcomes of those treatments
  + whether your ulcer has healed
  + whether there have been any other infections in your foot
  + whether you have had any operations on your foot

Again, most of this data will be available from your clinical records but if we can’t get all of the information we need (for example if you have been discharged from the diabetic foot clinic), we may need to contact you by phone or bring you see you in clinic.

* If you need to come for an extra clinic visit we can help with travel and parking costs.
* We will also ask if you would be willing to complete some questionnaires on your quality of life and your health care treatments at the time of developing high-risk features and at 4, 12, 24 and 52 weeks. The health care treatment questionnaire will also be completed at 8 weeks.
* Taking part in the questionnaires is optional and we will discuss this with you at the appropriate time. Questionnaires are available as either paper copies, or in electronic format via text message or email links as you prefer. The information from questionnaires allows us to determine if a new diagnostic strategy is safe and cost-effective for the NHS.
* Foot x-rays are part of your routine clinical care. Foot x-rays use ionising radiation to form images of your body to provide your doctor with clinical information. If you take part in this study you will not undergo any additional x-rays. Ionising radiation may cause cancer many years or decades after the exposure. The chances of this happening to you are the same whether you take part in this study or not.
* If Phase 2 of the study has been approved to start then we may ask if you would be willing to have an extra bone sample taken. We would discuss this with you in more detail at that time and provide you with further information.

**Can I choose which Phase of the study I join?**

No. When you come to clinic with a new DFU you will join the phase of the study which is active at that time. We are currently asking people to join Phase 1 of the study. You can only take part in Phase 1 once.

If you develop high-risk clinical features for a bone infection in the future, you may be able to take part in another phase of the study. You would be provided with a new information sheet with more information about that Phase of the study at that time. You would not be able to join the same Phase of the study more than once.

## You will continue to be looked after at the diabetic foot ulcer clinic and by the community team as normal. You will be given a patient identification card to have available at every appointment to let the diabetic foot ulcer clinic and the community team know you are part of the study. The research team will monitor your medical records and may also contact you if required for information at one of the timepoints mentioned above.

**How is my condition monitored?**

Phase 1 of the study is observational so we are not asking for any tests or treatments you wouldn’t otherwise receive. This means that all of the tests and treatments you receive will be chosen by your treating clinician, so there are minimal anticipated risks involved.  If you develop high-risk clinical features for infection during Phase 2 and are asked to take part in Phase 2 (once this Phase is approved to start), more information on the risks and benefits of the extra bone sample will be provided in a separate information sheet.

We are also asking you to give up some of your time to take part. Wherever possible your research appointments will be scheduled at the same time as your routine clinic appointment. However, you may be asked to attend an extra visit if we cannot get the necessary information from your medical records. Your travel and parking expenses will be paid if you need to come to the clinic for a visit which you would not normally have to attend as part of your routine care.

## What are the possible disadvantages and risks of taking part?

There are no direct benefits to being involved in the trial as we do not know how best to diagnose bone infection currently. However, participation in this study will help to answer this question and help us to improve the diagnosis and treatment of diabetic foot ulcers in the future and ultimately benefit other patients.

## What are the possible benefits of taking part?

## Expenses and payments

We anticipate that most of the information we need to collect in the study will be available from your medical records and will not provide payments for joining the study. However, should it be necessary for you to attend research specific visits then there is funding available to cover the costs of transport & parking.

**This completes part 1.**

***If the information in Part 1 has interested you and you are considering participation, please read on for additional information in Part 2 before making any decision.***

**PART 2**

Taking part in this study is entirely voluntary and you may stop taking part in all of this study, or in any part of it, at any time without giving a reason. However, we would like to know the reason if you are willing to say. Before deciding to stop, you should talk to your clinician or a member of the research team. They can advise you and may be able to deal with any concerns you may have. If you decide to stop taking part at any time it will not affect the standard of care you receive.

You can choose to;

* Stop completing questionnaires, but still take part in the rest of the study. You can change your mind later and start completing questionnaires again, if you want.
* Stop seeing the study team for visits or assessments, but allow us to continue collecting information about your health from medical records, via your GP or other contact between you and your hospital
* Stop study visits or assessments, and tell us not to collect any more information about your health from medical records. To make sure the research is still reliable, we need to keep the information we have already collected about you up to that point, and include it in the study analysis.

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

**What if there is a problem?**

It is very unlikely that you will come to any harm as a result of taking part in this study as all of the investigations are already used in the NHS every day. Your care and treatment, including any tests which may be undertaken (such as swabs/samples, blood tests, scans and x-rays) will remain the same as you would receive outside of the study. If you have any concerns about any aspect of this study, you should ask to speak with a member of your healthcare team.

Every care will be taken in the course of this study. However, in the unlikely event that you are injured as a result of the managing organisation (University of Leeds), compensation may be available, but you may have to pay your related legal costs. The hospital where you receive your treatment has a duty of care to you whether or not you agree to participate in the study, and the University of Leeds accepts no liability for negligence on the part of your hospitals employees. If you wish to complain about any aspect of the way you have been treated please contact your research clinician in the first instance. Any claims will be subject to UK law and must be brought in the UK. If you have private medical insurance, you should tell your insurer that you are taking part in research. They will let you know if it affects your policy.

Yes. If you decide to participate in DOMINO-DFU the information collected about you will be handled confidentially and strictly in accordance with the consent that you have given and relevant data protection laws, including the 2018 Data Protection Act.

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.

**Will my taking part in this study be kept confidential?**

**How will my information be used?**

We will take all necessary measures to ensure information about you is sent and stored securely by us or anyone acting on our behalf.

Information needed for the study will be entered directly into a secure database or collected on paper forms. Paper forms will be sent (using standard Royal Mail post or by a very secure internet method called secure file transfer) from the hospital to the Clinical Trials Research Unit (CTRU). You will be allocated a study number, which will be used with your date of birth and initials to identify you on each paper form. Your full name will be included on your consent form and a copy of this will be sent to CTRU by post or secure file transfer so we can check you have definitely agreed to take part in the study. This will be sent separately to any other study forms. All of your data will be entered onto a secure database held at CTRU.

Your full name, and preferred contact method details will be collected on a contact details form to enable CTRU to send questionnaires, reminder messages, updates about the study and other relevant items of interest, and study results to you (where you have indicated you would like to receive these). This form is sent to CTRU by post or secure file transfer. If you choose to update your contact details on our website, this information will be sent to the DOMINO-DFU study team at CTRU by email. An email account which can only be accessed by members of the DOMINO-DFU study team responsible for keeping contact details up to date will be used for this purpose only.

Every effort will be made to ensure that any further information about you that leaves the hospital will have information removed so that you cannot be recognised from it. This information will usually be removed by a member of the study team at your hospitals, but may also be removed by the CTRU upon receipt.

Your healthcare records may be looked at by authorised individuals from the research team, the University of Leeds (Study Sponsor) or the regulatory authorities to check that the study is being carried out correctly.

The research team at your hospital will use your name, NHS number, hospital number, address, phone number and email address to contact you about the study, to make sure the relevant information about the study is recorded for your care, and to oversee the quality of the study.

All the data we collect for this study will be made available to other researchers at the end of the study for additional research, including information you have already provided if you stop taking part. However, information will only be shared for worthwhile research projects with appropriate ethical approvals, in a way that you will not be identified, and only when we are sure your data will be managed correctly and securely. Sharing of clinical trial data is an important way we can make the most of the time and effort required to carry out trials.

**Involvement of your General Practitioner (GP) or Family Doctor:**

Your GP and the other healthcare professionals involved in your care will be kept informed of your participation in this study. A letter will be sent to your GP (with your agreement) to let them know you are taking part. If you take part in the Phase 2 high-risk group (when this is approved to start), a letter will be sent to your GP to let them know.

When the study is complete the results will be published in a medical journal, but no individual participants will be identified. If you would like to obtain a copy of the published results, please ask a member of the research team. A link to the published results will also be available on the DOMINO-DFU website <https://ctru.leeds.ac.uk/domino-dfu>. With your permission, we will send you information about the results by letter, text or email.

**What will happen to the results of this study?**

DOMINO-DFU is being funded by the National Institute for Health Research’s Advanced Fellowship Programme and is being organised by the Clinical Trials Research Unit at the University of Leeds. The study has been reviewed by the NHS National Institute for Health Research before funding was given. In addition, all research in the NHS is looked at by an independent group of people called a Research Ethics Committee. This committee exists to protect the safety, rights, wellbeing, and dignity of patients (Ethics ref: **21/PR/0407**). This research has also been reviewed by patients and carers.

**Who is organising and funding this research?**

**Study schedule (your routine appointments will continue as usual)**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **For all participants** | | | | | | | |
|  | | Start of data collection. Also known as ‘baseline’ or ‘ Day 0’ | Week 4 | Week 8 | Week 12 | Week 24 | Week 52 |
| Initial discussion | **✓** | **✓** |  |  |  |  |  |
| Completing a consent form |  | **✓** |  |  |  |  |  |
| Collect basic information about your wound |  | **✓** |  |  | **✓** | **✓** | **✓** |
| **If high-risk characteristics of infection develop:** | | | | | | | |
| Collect extra information about your wound**\*** |  | **✓** |  |  | **✓** | **✓** | **✓** |
| Completing questionnaires (this is optional)**\*** |  | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** |

\*Follow up dates will be based on the time you develop high-risk characteristics of bone infection, these may be different dates to the dates where we are collecting basic information.

**An example**

You attend the DFU clinic with a new DFU on 1st June 2021 and complete a consent form. Basic information about your wound will be collected on;

24th August 2021

16th November 2021

1st June 2022

You then develop high-risk characteristics of bone infection on 15th July 2021. Extra information about your wound & questionnaires (optional) will ***also*** be collected on;

12th August 2021 – questionnaires only

9th September 2021 – questionnaires only

7th October 2021

30th December 2021

15th July 2022

**PART 3: Extra information about data protection**

**General Information**

University of Leeds is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. University of Leeds will keep identifiable information about you for 15 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 <https://ctru.leeds.ac.uk/privacy/>.

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly funded organisation, we have to ensure that it is in the public interest when we use personally identifiable information from people who have agreed to take part in research. This means that when you take part in a research study, we will use your data in the ways needed to conduct and analyse the research study.

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interest of society as a whole. We do this by following the UK Policy Framework for Health and Social Care research.

If you wish to raise a complaint on how we have handles your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with the response or believe that we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner’s Office (ICO).

Our Data Protection Officer can be contacted using the following details

* Email: [DPO@leeds.ac.uk](mailto:DPO@leeds.ac.uk)
* General postal address: University of Leeds, Leeds LS2 9JT, UK
* Postal address for data protection issues: University of Leeds, Room 11.72 EC Stoner Building, Leeds, LS2 9JT
* Telephone number: +44 (0)113 243 1751

**How your information is used**

Individuals from University of Leeds and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Your hospital will pass these details to the University of Leeds. The only people in University

**Using your information for further research**

When you agree to take part in the study, you may also choose for the information about your health and care to be shared with 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 UK Policy Framework for Health and Social Care Research (<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/>).

This information would not identify you and would 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.

Please indicate on the consent form whether you are happy for anonymous data collected about you to be shared in the future. This is optional.

of Leeds who will have access to information that identifies you will be people who need to send you questionnaires and study information (if you choose to receive them).

The people who analyse the data will not be able to identify you and will not be able to find out your name or contact details.

University of Leeds will collect information about you from your medical records. This information will include your name, NHS number, contact details and health information, which is regarded as a special category of information. We will use this information in our analysis to determine the study results and to send you questionnaires and other study information.

Your hospital will keep identifiable information about you from this study for 15 years after the study has finished.