Fractured Ankle Management Evaluation

Chief Investigator: Associate Professor Xavier Griffin

PATIENT INFORMATION SHEET

We would like to invite you to take part in a research study investigating two different types of treatment for your broken ankle. Before you decide to participate in the study we would like you to understand why the research is being done and what it would involve for you. Someone from our team will go through the study information with you and answer any questions you might have.

What is the purpose of this study?

Ankle fracture is a very common injury. Treatments for ankle fractures aim to keep the bones in the right position while the breaks in the bones heal. For more severe fractures, like yours, treatment often involves an operation where cuts are made around the ankle, and plates and screws are fitted against the bone fragments to keep them in place. An alternative non-surgical treatment involves applying a snug plaster cast called a close contact cast, carefully shaped to your ankle, to hold the bones correctly while they heal.

This study will investigate whether the non-surgical treatment option will provide patients with comparable ankle function and quality of life to those treated with surgery.

Why have I been invited?

As you have broken your ankle you are eligible to be a part of this study. We expect that 40 hospitals across the country will be taking part in this study and we hope to recruit 890 patients with a similar injury to yours.

Do I have to take part?

No, it is entirely your decision whether you choose to take part or not. Throughout the study you are still free to withdraw at any time and without giving a reason. Should you wish to withdraw, simply contact the study office or Trial Manager on 01865 223113 or email fame@ndorms.ox.ac.uk and a staff member will guide you through the withdrawal process. Alternatively you may wish to contact your local research lead who will assist you.

A decision to withdraw at any time or a decision not to take part will not affect the standard of care you receive. However, we will not be able to remove the data we have already collected prior to your decision to withdraw.

What will happen if I decide to take part?

If you decide you would like to be involved in the study you will be asked to sign a consent form. You will then be treated with either:

(a) an operation where cuts are made around the ankle and the broken bones are held using plates and screws.

(b) a procedure where your ankle bones are realigned in theatre and a special, snug plaster cast called a close contact cast is applied.

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In both cases you will need to have a general anaesthetic and the procedure will be done in an operating theatre.

In this study we use a process called randomisation. Randomisation means that each treatment is given to a similar mix of patients to make sure any difference between the treatments is not due to anything else, like their age, gender or where they live. So the patient, nurse or doctor do not make the decision. That way none of us can unconsciously choose healthier or younger people for example to receive one of the treatments. Using this method will ensure that, at the end of the study, the people in the two groups are very similar – the only difference between them is the type of treatment they received. When we compare the two groups it is a fair comparison of the treatments.

You will be followed up according to the usual schedule at your hospital, in the same way as patients who are not in this study. The only additional commitment we would ask of you would be to fill out a questionnaire at the start of treatment and on three occasions during your recovery.

After signing the consent form, we will ask you to fill out the first questionnaire. The questionnaire will ask you about how well you were able to perform day-to-day tasks and how you were feeling before your injury. The questionnaire will take approximately 15 minutes to complete.

After you leave the hospital, your hospital doctor will arrange to see you at regular intervals for routine check-ups. We will follow how your recovery progresses over the next 12 months. The research team will obtain relevant information from your hospital records to see how you are getting on. This will include information about how long you spent in hospital, what treatments you required and how well you recovered. We will also use records from routinely collected databases to get information about any existing medical problems you have, any further treatments you have needed for your ankle or other medical conditions and any complications you have suffered. We can take this information into account when analysing the results of the study and to look at the cost to the NHS.

We will ask you to fill out a questionnaire at 8 weeks, 4 months and 12 months after your injury (see flowchart on next page). The questions will be very similar to those asked at the start of the study. We will send you a weblink to the questionnaire electronically by email or text message. At 12 months we will also be interested to hear about your experience of being in the study and will ask you some questions about this.

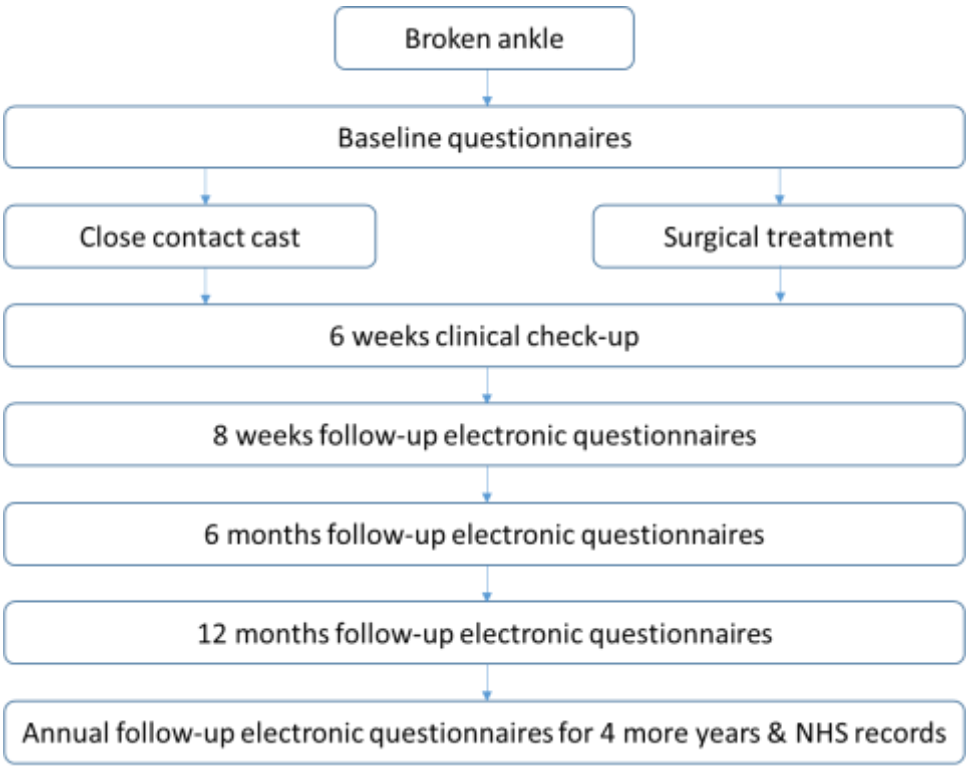
We will also send you short questionnaires about how well your ankle is working every year for four more years. Finally, we will get routine NHS information collected about you over the next five years to see what the long-term outcomes are following your injury.

If you have no smartphone or access to a computer, we will phone you to ask the questions on the questionnaires. We may also phone you if we need to clarify any of your responses. Later in the study we may send you questionnaires by post, and for this we are collecting your postal address.

What are the possible disadvantages and risks of taking part?

The risks of the injury itself are the same for both groups of patients in the study, and are the same as for patients who are not taking part in the study. Both treatments are used across the NHS currently and are not new or experimental.

There is a small risk of complications if you have the operation, such as infection and prominent metalwork, as with any surgery. We expect that some patients will need to return for a further operation. The specific risks of surgery would not apply with the close contact cast. The main potential risk of the cast treatment is that the bones move out of place, which may require further treatment, and that might be an operation. It is also possible that while you are under anaesthetic, the surgeon decides he or she cannot hold your bones into the right position satisfactorily with the cast, and you would then receive an operation straight away.



Flowchart: FAME schedule

What are the possible benefits of taking part?

Both treatments are used across the NHS so there is no specific advantage to you for taking part in the study. However, you will help us improve treatment for future patients with similar injuries. The study will also provide valuable information on the best use of resources within the NHS.

What if new information becomes available?

Sometimes during the course of a research study, new information becomes available about the treatment that is being studied. If this happens, the research team will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, we will encourage you to discuss your continued care with your doctor. If you decide to continue in the study you will be asked to sign an updated consent form.

What happens if something goes wrong?

The University of Oxford is the Sponsor for the study and has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. If you wish to discuss any aspect of the way in which you have been approached or treated during the course of this study, you should contact Associate Professor Xavier Griffin who is the overall lead of this study on 01865 223116; or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480 or email ctrg@admin.ox.ac.uk. NHS indemnity covers any other treatment with which you are provided.

What will happen to the information I give?

Your personal details will be held by the research team at University of Oxford. We will remove any details that would identify you personally (such as your name, date of birth, etc.) from your answers to our questions and no individual results will be published.

We will share limited personal information (your NHS number, gender, date of birth and postcode) with appropriate organisations (including, but not limited to, NHS Digital, National Services Scotland (NSS), Office of National Statistics, Clinical Practice Research Datalink) in order to link your study data to specific records related to the research held in other databases. This will allow bodies such as NHS Digital, National Services Scotland (NSS), Office of National Statistics, Clinical Practice Research Datalink to provide us with a temporary linkage dataset containing your medical data with identifying information removed, that will only identify you by your study ID.. Although it is extremely unlikely to affect you individually or as a result of your ankle injury, over the time period of this study it is possible that some participants may die. We plan to collect this more sensitive information just so that we can perform the analyses more accurately. Once the linkage is complete, the temporary linkage dataset will be destroyed. All information that is collected during the course of the research will be used and stored in accordance with the most up to date data protection legislation.

What happens to my personal data?

Any data from which you can be identified, such as your name, gender, date of birth, or data concerning your health, is known as personal data. The University of Oxford, as sponsor, is the data controller. This means that the University of Oxford is responsible for looking after your information and using it properly. We will use the minimum personally-identifiable information possible. The University of Oxford is working with other NHS and research organisations to deliver this study:

- University of Bristol, Musculoskeletal Research Unit
- South Tees Hospitals NHS Foundation Trust
- University of Warwick, Clinical Trials Unit

Members of the study team from these organisations will only have access to de-identified and aggregated data for the purposes of contributing to the oversight, analysis and reporting of the study.

We will keep any research documents with identifiable information about you for 12 months after the study has finished. Your contact details will be kept until the long-term follow up is completed (5 years after treatment). We will store the anonymised research data securely at the University of Oxford for a minimum of 5 years after publication of the results of the study. You have the right to access, change or remove your contact details. Your rights to access, change or remove your NHS number (or equivalent), gender, date of birth and postcode, and data concerning your health, are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate, and restricting its use would seriously impair its use for research purposes.

Your personal data will only be used as we explained it in this information sheet, and research is a task that we perform in the public interest. If you are concerned about how your personal data is being used, please contact the study team using the contact details at the end of this information sheet.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at https://compliance.admin.ox.ac.uk/research-data

The lawful basis for the processing of your personal data is governed by the General Data Protection Regulation (GDPR) Articles 6 & 9. The University of Oxford will not transfer your personal data to any third countries or international organisations.

What will happen to the results of the study?

This study is expected to last 8 years. We will publish the findings of the study at the end of the study in medical journals and at medical conferences. The FAME study has a webpage which contains updates on study progress and further information and is available at www.famestudy.org. Once the study is finished the results will be available to you online on this website (www.famestudy.org). All results will be anonymised.

How have patients and the public been involved in this study?

We value the patient perspective which has been key in the development of this research. Our patient representative has reviewed this Patient Information Sheet and all FAME patient facing documents. Participants' views will continue to be represented throughout the study. Additionally, the oversight committees, that will regularly review the study progress, include at least one patient representative who will be involved in discussion and decision making throughout the duration of the study.

If you would like to know more about getting involved in research as a patient or member of the public, please see this link: https://www.nihr.ac.uk/patients-and-public/.

Who has reviewed this study?

This study has been reviewed by the East Midlands – Leicester Central Research Ethics Committee and approval was given on 14 August 2019. This study is supported by a grant from the National Institute for Health Research.

Contacts for further information

If, at any time, you would like further information about this study you may contact the Trial Manager by telephoning 01865 223123 or emailing fame@ndorms.ox.ac.uk. Or you can contact your local research lead or Associate Professor Xavier Griffin, who is the overall lead of this study on 01865 223116. For further details of the study and our full privacy notice you can also refer to our study website www.famestudy.org.

The PALS service (PASS in Scotland) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS and PASS can give general advice, however they will not be able to give specific information regarding this study.

To see the FAME website on your mobile device, scan this QR code: