[Local NHS trust logo]

# TrAFFix – Trial of Acute Femoral Fracture Fixation

# Consultee Information Sheet

What is a consultee?

The Mental Capacity Act 2005 is a piece of legislation that protects the rights of people who are not able to make decisions for themselves. The Act includes safeguards for the conduct of research involving people who may, temporarily or permanently, not be able to consent due to a medical problem, for example because of learning disabilities, illnesses such as dementia, head injuries or mental health problems.

In particular, the Act requires that before a person who is unable to consent is involved in a trial, another suitable person must be identified who can act on their behalf as a consultee. This consultee can then advise the research team on whether, in their opinion, the person who lacks capacity would want to be in involved in the project.

Why have I been approached to act as a consultee?

A personal consultee may be someone who has a personal relationship with the patient but does not have a conflict of interest such as being part of the research or gaining financial benefit. Examples of suitable people who might act as a personal consultee are:

- A family member, carer or friend
- A court appointed deputy who has a personal relationship with the participant

When reasonable steps have been taken to identify a personal consultee and a personal consultee is unavailable, then the researcher must nominate a person to act as a consultee. This person may be involved in patient's care in a professional capacity but they must have no connection with the research project. A suitable person who might act as a nominated consultee is a:

- General practitioner, or independent orthopaedic surgeon

What are the duties of a consultee?

The main responsibility of a consultee is to advise the research team as to whether or not they think that the participant would be happy to take part in the trial. This means that you agree to be consulted by the research team to establish whether, in your opinion, the participant might agree to take part in the research. You are not being asked to give consent on behalf of the participant; however, if you advise us that the participant would not want to be part of the trial then we will abide by this.

In order to help you make the decision about acting as a consultee and to advise the research team about the patient's wishes, the remainder of this information sheet describes what is involved in the trial. This information is the same as the information given to patients who are able to make this decision for themselves.

# TrAFFix – Trial of Acute Femoral Fracture Fixation

## Patient Information Sheet

### Background information

We would like to invite you to take part in a research study investigating two commonly used ways of fixing a break or fracture at the bottom end of the thigh bone. Before deciding, we would like you to understand why the research is being done, and what it would involve if you agree to take part.

### Purpose of the trial

This is a small study to help us plan a larger study that will compare two different methods used to treat breaks at the bottom end of the thigh bone. It is important for you to know that both methods are already routinely used across the NHS, but we don't know whether one is better than the other.

In this small preliminary study we will work out the best way to collect the information we need to answer our research question, and how many patients we would need in the larger study. In the larger study we will then compare the two techniques to see whether the method of treating the fracture has any effect on patients' quality of life. We will also investigate whether one method is better at helping the break to heal or results in fewer complications, and whether one method is better value for money.

### Why have I been invited to take part?

We decided to invite you to take part because you have broken your thigh bone and your surgeon feels that you are likely to benefit from surgery.

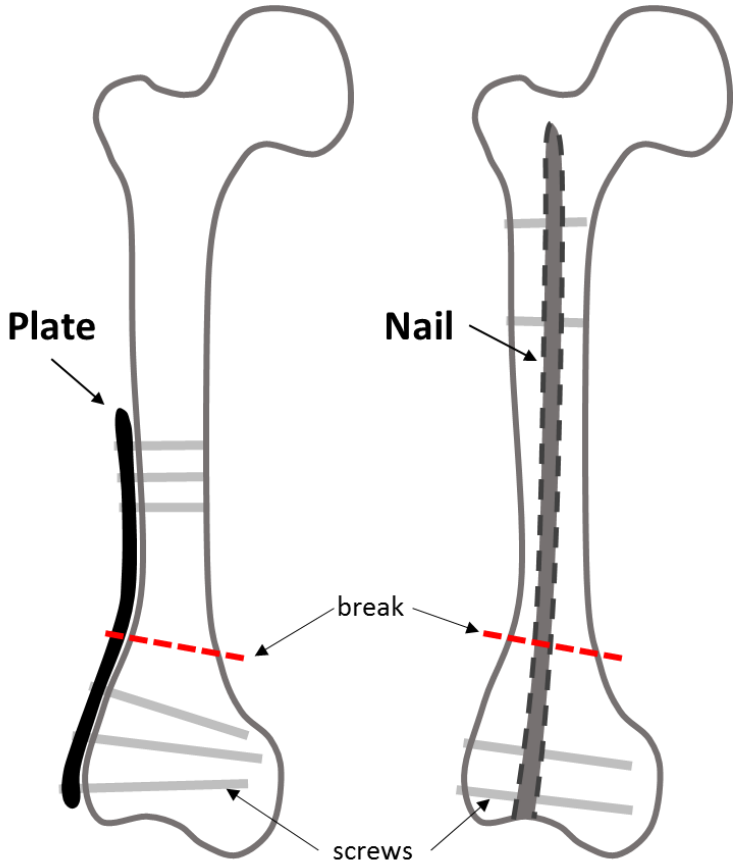
This hospital is one of several across the country that are taking part in the study, and most patients with fractures at the end of their thigh bone who are treated at those hospitals will be asked to take part.

### What is the difference between the two techniques?

Both methods involve surgery to attach a support to the broken bone that allows the bone to heal in the correct position. One method uses a metal nail that goes through the middle of the bone, while the other method uses a metal plate that attaches to the outside of the bone.

With the nail method, a metal nail is inserted into the hollow space in the middle of the bone, and passed across the fracture. Screws are then inserted into the nail on either side of the broken section. With the metal plate method, a metal support is attached to the outside of the bone, across the broken area, and screwed into place on either side of the fracture. The diagrams on the next page give an idea of what each method looks like.

The rehabilitation program for both methods will be the same. Your doctor and rehabilitation team will advise you on the type of exercises you should be doing after your operation.




What happens if I say yes?

If you decide to take part in the study you will be asked to sign a consent form that confirms you have understood the information on this sheet, and have had an opportunity to ask any questions that you might have. We will then ask you to fill out a questionnaire with questions regarding pain, how well you can do certain day-to-day tasks and how you are feeling. You will then be prepped for surgery as usual and your surgeon will carry out one of two treatments, assigned randomly.

All patients with a broken leg are followed up carefully to make sure that their break is healing properly. After your operation your surgeon will arrange follow-up visits as per normal standard practice; you will not be required to come in for any extra visits for the research study. We will ask you to complete a further questionnaire when you attend your follow-up visits at 6 weeks and 4 months after you broke your leg. Alternatively we may post you copies of the questionnaires and ask you to return them to us using a pre-stamped envelope. The questionnaires will take approximately 10-20 minutes to complete, and will have similar questions each time.

If we don't receive your questionnaires then we may contact you by phone, email or text message to check we've got the correct contact details. To do this we will need to collect some identifying information, which will be stored at the University of Oxford. We will also collect a copy of the consent form for monitoring purposes. Any information will be treated with the strictest security and confidentiality.

As part of the trial we will collect the results of some tests that will have been done as part of your usual care. This includes the results of routine X-rays from before your surgery, and about

6 weeks after your surgery. We will also collect a record of your rehabilitation and any complications that arise.

As part of this preliminary study, we would like to understand more about participants' experiences of being involved in this trial. Therefore, we will invite some patients to take part in telephone or in-person interviews, where a researcher will ask about what it was like to take part in this research.

Which treatment will I be given?

Your treatment group will be allocated using a computer once you have agreed to take part. The computer does not keep any information that identifies you, and you will have an equal chance of being allocated either treatment. Your surgeon will know which group you are in, and if you wish to know you can ask a researcher or a member of your care team to find out for you once the study is complete.

Do I have to take part?

No. It is entirely your decision whether to take part or not. If you agree to take part now, you will be able to withdraw your consent at any time without giving a reason and without affecting the care you will receive.

If you do choose to withdraw, we will ask whether we can use some of your information that is relevant to our research study that will be collected as part of your routine medical care. We would also be interested to ask you about your reasons for your decision and if you agree we may approach you for an interview in the future.

What are the possible disadvantages and risks?

As with any major operation, surgery carries some risks of bleeding, blood clots, damage to nerves and blood vessels, and risks associated with anaesthetic. These risks are similar for both treatment options and are the same if you choose not to participate in this research.

As part of your normal treatment you will have some routine X-rays taken of your leg, both before surgery and during your recovery. The dose of radiation you will receive is the same as about 3 days of normal background radiation. The dose will be the same whether or not you decide to participate in the trial.

What are the possible benefits of taking part?

There are no specific benefits to you for taking part in this trial. However, the information that we get from this trial should help us with the development of the bigger trial, which we hope will ultimately provide an answer about the most suitable treatment for this type of injury.

What happens after the trial?

After you have completed your 3rd questionnaire (at around 4-months after surgery) you will have completed your involvement in the trial. During and after this time your care will be managed by your surgeon and your clinical care team.

Will my information be kept confidential?

Your anonymised data and personal details will be held securely and separately in access-restricted electronic databases and filing systems by the research team at the University of Oxford and only looked at by authorised members of the research team, regulatory bodies, and participating NHS organisations when it is relevant to your participation in this research. Personal information (e.g. contact details) will be destroyed at the end of the trial, and other anonymised data will be stored for 5 years from the end of the trial. Your information will not be released to anyone not involved in the study or used for any purpose not described here. It will not be possible to identify individual patients from any report or publication of the results of this study.

With your consent we will notify your GP and other doctors, who may have treated you but who are not part of the research team, of your participation. If we have trouble contacting you during follow-up we may ask your GP or central NHS organisation to confirm your contact details.

What if new information becomes available?

If there is important new information about the treatments being studied then 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 continue in the study you may be asked sign an updated consent form.

What if something goes wrong?

The University of Oxford is the Sponsor for this research, and so has appropriate insurance in place in the unlikely event that you suffer any harm as a result of your participation. NHS indemnity covers you for the clinical treatment you receive.

What if I have concerns?

If you have concerns about any aspect of this research study you can contact Mr Xavier Griffin, who is an Associate Professor of Orthopaedic Trauma at the University of Oxford, and is in charge of this trial and responsible for its conduct. Mr Griffin can be contacted on 01865 223116 or xavier.griffin@ndorms.ox.ac.uk. You can also contact the University of Oxford Clinical Trials and Research Governance (CTRG) office, who are responsible for overseeing all clinical trials sponsored by the University of Oxford. The CTRG office can be contacted on 01865 857939 or ctrg@admin.ox.ac.uk.

Who has reviewed this trial?

This trial has been reviewed by the Wales Research Ethics Committee 5, and was approved on 01/08/2016 with reference number 16/WA/0225.

Contacts

If you would like more information you can contact [name of local contact] (your local research lead) on [phone number] or [email address], or Robin Lerner (the coordinator of this trial from the University of Oxford) on 01865 227912 or traffix@ndorms.ox.ac.uk.

For independent advice you can contact your local Patient Advice Liaison Service (PALS), which can provide support for complaints or queries you may have about the care you receive as an NHS patient. PALS can give general advice, but will not be able to give specific information about this trial. Your local PALS can be reached on [phone number] or [email address].

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# TrAFFix – Trial of Acute Femoral Fracture Fixation

## Retrospective Consultee Information Sheet

What is a consultee?

The Mental Capacity Act 2005 is a piece of legislation that protects the rights of people who are not able to make decisions for themselves. The Act includes safeguards for the conduct of research involving people who may, temporarily or permanently, not be able to consent due to a medical problem, for example because of learning disabilities, illnesses such as dementia, head injuries or mental health problems.

In particular, the Act requires that before a person who is unable to consent is involved in a trial, another suitable person must be identified who can act on their behalf as a consultee. This consultee can then advise the research team on whether, in their opinion, the person who lacks capacity would want to be in involved in the project.

Why have I been approached to act as a consultee?

A personal consultee may be someone who has a personal relationship with the patient but does not have a conflict of interest such as being part of the research or gaining financial benefit. Examples of suitable people who might act as a personal consultee are:

- A family member, carer or friend
- A court appointed deputy who has a personal relationship with the participant

When reasonable steps have been taken to identify a personal consultee and a personal consultee is unavailable, then the researcher must nominate a person to act as a consultee. This person may be involved in patient's care in a professional capacity but they must have no connection with the research project. A suitable person who might act as a nominated consultee is a:

- General practitioner, or independent orthopaedic surgeon

What are the duties of a consultee?

The main responsibility of a consultee is to advise the research team as to whether or not they think that the participant would be happy to take part in the trial. This means that you agree to be consulted by the research team to establish whether, in your opinion, the participant might agree to take part in the research. You are not being asked to give consent on behalf of the participant; however, if you advise us that the participant would not want to be part of the trial then we will abide by this.

In order to help you make the decision about acting as a consultee and to advise the research team about the patient's wishes, the remainder of this information sheet describes what is involved in the trial. This information is the same as the information given to patients who are able to make this decision for themselves.

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# TrAFFix – Trial of Acute Femoral Fracture Fixation

## Retrospective Patient Information Sheet

### Background information

After careful consideration we have included you in a research study comparing two commonly used methods of fixing a break or fracture at the bottom end of the thigh bone. Due to the emergency nature of your injuries we were not able to give you details of the study before your operation.

Before deciding whether you would like to continue to take part, we would like you to understand why the research is being done, and what it would involve if you agree to take part.

### Purpose of the trial

This is a small study to help us plan a larger study that will compare two different methods used to treat breaks at the bottom end of the thigh bone. It is important for you to know that both methods are already routinely used across the NHS, but we don't know whether one is better than the other.

In this small preliminary study we will work out the best way to collect the information we need to answer our research question, and how many patients we would need in the larger study. In the larger study we will then compare the two techniques to see whether the method of treating the fracture has any effect on patients' quality of life. We will also investigate whether one method is better at helping the break to heal or results in fewer complications, and whether one method is better value for money.

### Why was I chosen?

You were eligible to take part in the study because you sustained a break to the end of your thigh bone, which your surgeon felt would benefit from surgery. You were included after the clinical team discussed the study with either your relative or your treating doctor.

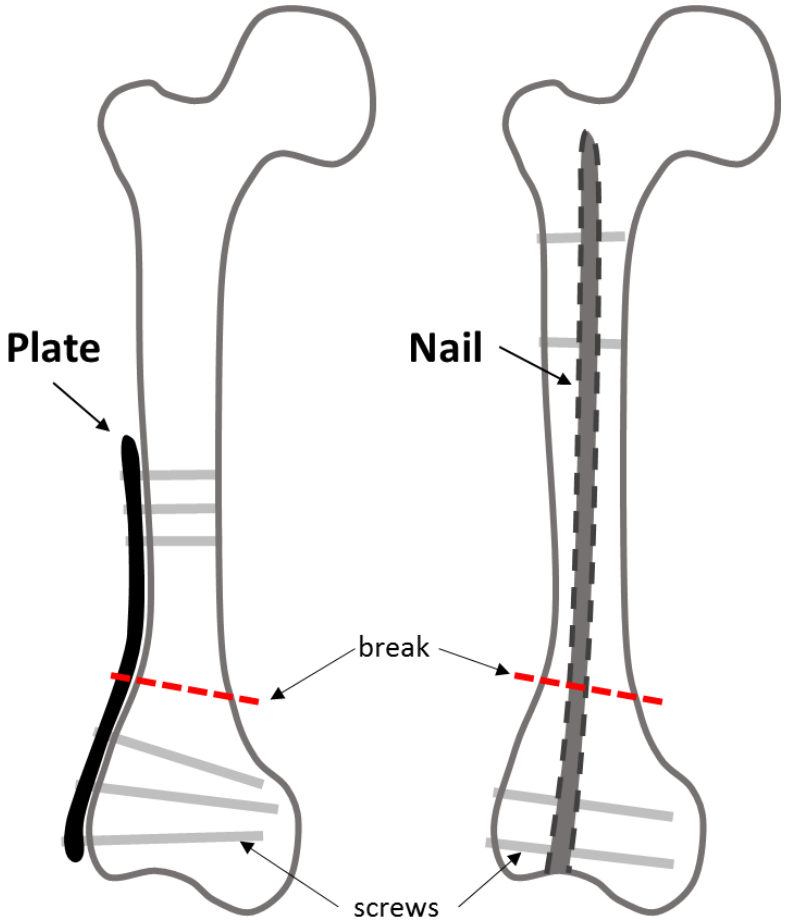
This hospital is one of several across the country that are taking part in the study, and most patients with breaks at the end of their thigh bone who are treated at those hospitals will be asked to take part.

### What is the difference between the two techniques?

Both methods involve surgery to attach a support to the broken bone that allows the bone to heal in the correct position. One method uses a metal nail that goes through the middle of the bone, while the other method uses a metal plate that attaches to the outside of the bone.

With the nail method, a metal nail is inserted into the hollow space in the middle of the bone, and passed across the fracture. Screws are then inserted into the nail on either side of the broken section. With the metal plate method, a metal support is attached to the outside of the bone, across the broken area, and screwed into place on either side of the fracture. The diagrams on the next page give an idea of what each method looks like.

The rehabilitation programs for both methods are same. Your doctor and rehabilitation team will advise you on the type of exercises you should be doing after your operation.




Which treatment was I given?

Whether your fracture was fixed using a plate or a nail was random and was allocated by a computer. The computer does not keep any information that identifies you, and you had an equal chance of being given either treatment. Your surgeon will know which group you are in, and if you wish to know you can ask a researcher or a member of your care team to find out for you once the study is complete.

What happens if I say yes?

If you decide to continue taking part in the study you will be asked to sign a consent form that confirms you have understood the information on this sheet, and have had an opportunity to ask any questions that you might have. We will then ask you to fill out a questionnaire with questions regarding pain, how well you could do certain day-to-day tasks and how you were feeling before the fracture.

All patients with a broken leg are followed up carefully to make sure that their break is healing properly. Your surgeon will arrange follow-up visits as per normal standard practice; you will not be required to come in for any extra visits for the research study. We will ask you to complete a further questionnaire when you attend your follow-up visits at 6 weeks and 4 months after you broke your leg. Alternatively we may post you copies of the questionnaires and ask you to return them to us using a pre-stamped envelope. The questionnaires will take approximately 10-20 minutes to complete, and will have similar questions each time.

If we don't receive your questionnaires then we may contact you by phone, email or text message to check we've got the correct contact details. To do this we will need to collect some identifying information, which will be stored at the University of Oxford. We will also collect a copy of the consent form for monitoring purposes. Any information will be treated with the strictest security and confidentiality.

As part of the trial we will collect the results of some tests that will have been done as part of your usual care. This includes the results of routine X-rays from before your surgery, and about 6 weeks after your surgery. We will also collect a record of your rehabilitation and any complications that arise.

As part of this preliminary study, we would like to understand more about participants' experiences of being involved in this trial. Therefore, we will invite some patients to take part in telephone or in-person interviews, where a researcher will ask about what it was like to take part in this research.

Do I have to continue to take part?

No. It is entirely your decision whether to continue to take part or not. If you agree to take part now, you will be able to withdraw your consent at any time without giving a reason and without affecting the care you will receive.

If you do choose to withdraw, we will ask whether we can use some of your information that is relevant to our research study that will be collected as part of your routine medical care. We would also be interested to ask you about your reasons for your decision and if you agree we may approach you for an interview in the future.

What are the possible disadvantages and risks?

As with any major operation, surgery carries some risks of bleeding, blood clots, damage to nerves and blood vessels, and risks associated with anaesthetic. These risks are similar for both treatment options and are the same if you choose not to participate in this research.

As part of your normal treatment you had some routine X-rays taken of your leg before surgery, and you will have more taken during your recovery. The total dose of radiation you will receive is the same as about 3 days of normal background radiation. The dose will be the same regardless of your participation in the trial.

Possible benefits of taking part?

There are no specific benefits to you for taking part in this trial. However, the information that we get from this trial should help us with the development of the bigger trial, which we hope will ultimately provide an answer about the most suitable treatment for this type of injury.

What happens after the trial?

After you have completed your 3rd questionnaire (at around 4-months after surgery) you will have completed your involvement in the trial. During and after this time your care will be managed by your surgeon and your clinical care team.

Will my information be kept confidential?

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