

TrAFFix – Trial of Acute Femoral Fracture Fixation

Interviews – Information Sheet

Background information

You were previously approached about being part of further research as part of the TrAFFix study, which is aiming to understand more about how breaks of the thigh bone should be treated. We would like to hear more about your experience of being injured, having treatment, and your impressions of this research, by inviting you to be interviewed by a member of our research team. Before deciding whether to take part in an interview, we would like you to understand why these interviews are being done, and what it would involve if you agree to take part.

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.

You will be invited to discuss your experience in an open and relaxed way with a trained interviewer from the TrAFFix team. The interview should take about 30 minutes, and will be done in person or over the phone. A researcher will contact you to agree a convenient time and place.

The interviews will consist of questions about what your experience of taking part in this research has been like, for example how you felt about being asked to take part, what you thought of the information provided, and how much extra work it was. The researcher may ask to interview you up to two more times over the course of the study.

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. If you agree to be interviewed now, you can decline to take part in further interviews later in the study.

Possible benefits of taking part?

There are no specific benefits to you for taking part in these interviews. However, the information that we get should help us with the development of the bigger trial, which will provide information about how to treat breaks of the thigh bone.

Will my information be kept confidential?

Your answers to the questions will be audio recorded, and later typed in to a computer with all the personal details removed. Your anonymised data and any personal details will be held securely and separately in access-restricted electronic databases and filing systems by the University of Oxford, and only looked at by authorised members of the research team and regulatory bodies 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.

We may use anonymised quotes from your interview in reports or publications, but it will not be possible to identify individual participants from any report of publication of the results of this study.

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 ctrq@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 researcher] (the researcher in charge of the interviews) 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.

TrAFFix – Trial of Acute Femoral Fracture Fixation

Interviews – Staff Information Sheet

Background information

The TrAFFix feasibility study is comparing locking plates with intramedullary nails for fractures of the distal femur. As part of this trial we are undertaking a process evaluation to help us identify potential barriers to running a larger, definitive trial. The input of staff taking part in the feasibility study will be key to the success of the process evaluation and planning a larger study. We would like to hear more about your impressions of this research by inviting you to an informal interview with a qualitative researcher. Before deciding whether you would like to be involved, we would like you to understand why these interviews are being done, and what it would involve if you agree to take part.

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.

You will then be invited to discuss your experience in an open and relaxed way with a trained interviewer from the TrAFFix team. The interview should take about 30 minutes, and will be done in person or over the phone. A researcher will contact you to agree a convenient time and place.

The interviews will consist of questions about what your experience of taking part in this research has been like, for example what you thought of the information provided, and how much extra work it was. As the research study progresses, you might change your views on certain aspects of the trial. The researcher may therefore ask to interview you again during the study.

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. If you agree to be interviewed now, you can decline to take part in further interviews later in the study.

Possible benefits of taking part?

There are no specific benefits to you for taking part in these interviews. However, the information that we get should help us with the development of the bigger trial, which will provide information about how to treat distal femur fractures.

Will my information be kept confidential?

Your answers to the questions will be audio recorded, and later typed in to a computer with all the personal details removed. Your anonymised data and any personal details will be held securely and separately in access-restricted electronic databases and filing systems by the University of Oxford, and only looked at by authorised members of the research team and

regulatory bodies 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.

We may use anonymised quotes from your interview in reports or publications, but it will not be possible to identify individual participants from any report of publication of the results of this study.

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