**SUMMARY**

*… Can you help with our important research study?*

…Before you say yes, it’s important you understand what this involves. Please read the following information carefully, discuss with others if you wish, and ask us any questions you have.

**-** We are comparing two methods of fixing broken shin bones.

**-** Commonly we treat broken shin bones by attaching a frame to the outside of the leg which goes into the bone. This frame is fixed firmly in place, ensuring the broken bone cannot move as it heals. This is the one method we will use.

**-** Recent research in animals suggests that better results could be achieved if the frame is kept slightly loose for the first few weeks, allowing for the bone to heal more before it is set firmly in place. This is the other method we will use. This method has been used in humans safely, but so far no one has measured whether it is better or worse than the current treatment. This is what we intend to do.

**-** Patients who agree to take part in the trial will receive either the normal rigid frame, or a frame that is fixed marginally looser initially. Those with the more loose frame will have an x-ray after 2-3 weeks, and at that point they will have their frame tightened. Apart from this, all the patients will receive the normal level of care. Both frames should still allow you to walk on the leg as your pain eases.

**-** You will be seen regularly up until at least 1 year after your injury to see how you are getting on. You will also be asked to complete questionnaires about your experience, to help with our study.

**-** Any treatment option has risks. Your surgeon will discuss the potential risks involved with your options so that you can make an informed decision.

**-** It is completely up to you to decide if you want to take part. At any point you can change your mind - if you do your care will not be affected.

**-** If you are under 18 we would encourage you to discuss this with a parent/guardian.

**-** In this study we will use information from you and your medical records. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.

**-** Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

**-** At the end of the study we will save some of the data in case we need to check it or use it for future research. We will make sure no-one can work out who you are from the reports we write.

The information pack tells you about the trial in more detail

**CLINICAL TRIAL:
Assessment of Bone Healing Time in Tibial Fractures; Static Vs Variable Dynamization External Fixation - A Multi-Centre Randomised Controlled Trial**

**INFORMATION PACK**

**CONTENTS OF THIS DOCUMENT**
**1. Why are we doing this study?

2. What would taking part involve?

3. What are the possible benefits of taking part?

4. What are the possible risks?

5. More information

6. How to contact us**

**1. Why are we doing this study?**

**Broken shin bones**

Broken shin bones are usually fixed with an operation which involves fixing the bone in place with a metal structure. These structures are usually either a metal rod on the inside of the bone, or a frame structure attached to the bone on the outside of the leg.

*When this works as planned, it still may take a while for the leg to return to normal. Very Occasionally this doesn’t completely fix the problem, or other issues can occur. This may affect your ability to move your leg properly, which can have a big effect on your quality of life. We are looking to see if we can improve these outcomes.*

**What is the purpose of the study?**
The overall aim of surgery is to heal the bone in the correct place, so that it can return to its normal function.

Currently the metal structures we use hold the bones rigidly in place. Instead of fixing the bone rigidly, recent thinking would suggest that it may be beneficial to allow some small movements of the fracture at its early stages, to help the bone to heal better. This has led to the development of what is called reverse dynamization. Reverse dynamization is a technique where the frame allows some small movement of the bones when the fracture is first fixed, then after 2-3 weeks the bone is fixed firmly in place. This is easily achieved with the metal frame, as the frame can be adjusted from the outside. This new technique has shown good results in animals and has been used successfully in humans.

We will compare this new method of reverse dynamization to the normal practice of rigid fixation, to assess if there is any difference in outcomes, or the time it takes for the bone to heal. This will be the first trial to compare the two treatments.

**Why have I been invited to take part?**
You have been invited to take part in this study as you have recently broken your shin bone, are awaiting treatment, and are suitable for this study. Both methods of fixation are suitable for you and the surgeon carrying out the operation is an expert in treating these injuries.

**2. What would taking part involve?**
We would encourage you to take your time to consider your enrolment. We advise anyone under the age of 18 to discuss with a parent or guardian if possible.

After reading this and discussing any questions you have, if you decide to participate you would sign a form to say you agree, followed by a quick questionnaire. Then you would be randomly allocated to receive one of the two treatments. You have a 50/50 chance of receiving either one. In this way the data will be kept fair and scientific. We would also need you to sign another form agreeing to have the procedure – this always happens for any surgical procedure irrespective of this study - it ensures you understand the risks and benefits of the surgery.

After this you would undergo the treatment, as detailed below.

The standard of care you would receive would be the same whether you are part of the trial or not.

**Treatment**

*- Option 1*: *Static fixation (SF) using external frame* - If allocated to this group, you will receive surgery to fix the broken bone with a metallic frame around the outside of your leg. This frame extends into your foot for a period of time while the bone heals. The surgeon will be responsible for adjusting and monitoring the frame. You will be allowed to move your leg and put weight through it as tolerated. No plaster cast is needed. This is routinely performed, and your management will follow normal clinical practice for the hospital.

*- Option 2:* *Variable Reverse Dynamization (RD) using external frame* - This will use the same operation and frame as the first group. The difference being that the settings on the metal frame will make sure the frame is less rigid for the first few weeks. You shouldn’t be able to physically notice the difference, and you will still be allowed to move and walk on it as tolerated, with no need for a plaster cast. Again, the surgeon will be responsible for altering the settings on the frame. After 2-3 weeks an x-ray scan will be performed to see if the bone has started to grow back, once this is the case the frame will be adjusted from the outside to become more rigid. This is not the normal management strategy.

- Routine physiotherapy: Both groups will see physiotherapists at the hospital and in their follow up appointments, to help with exercising the leg. This is part of normal practice.

- Follow up: after the operation, you will be seen 2 weeks afterwards in the hospital clinic, then again at 3 weeks, then 6 weeks, then every 6 weeks until the broken bone has healed. You will be seen again after a year, and if there are no problems at this point you will be discharged. All of this is the standard procedure for patients with this injury.

- Xray scans: You will have already had a scan to show us your broken bone. You will receive another scan during the operation, and another one at each of your follow up appointments. In total the average amount is usually 8-10. This is the standard practice. Additional to this, if you are receiving the new reverse dynamization treatment option then you will receive one more x-ray scan before we change the settings on the frame. This extra x-ray is not normally performed as part of standard care

**Questionnaires and Records**
You will be asked to complete a questionnaire at 0, 3, 6, and 12 months so that we can assess your recovery after your treatment. The study team can help you complete them over the telephone if needed. These should each take around 15-30 minutes.
We will collect data from your hospital about your injury, any other treatments you have received, and any complications that have occurred, as well as your X-ray/CT imaging results. These questionnaires are a research activity and therefore not something we usually do. With your consent we would also like to send you questionnaires after the 12month follow up period, this is however completely optional and will not affect your participation in any way if you decide not to.

**How will I be contacted?**
With your permission we may contact you via: *Post* to send you questionnaires and newsletters; *Telephone* to remind you about questionnaires; *Email* with updates.

**Withdrawal from the study**
You do not have to take part if you do not want to.
If you decide to take part now, you can always change your mind at any point and withdraw from the study. You do not have to give a reason for this. Your rights and your care would not be affected.

If you were to withdraw, we would ask you tell us if you would not want us to contact the hospital for any more information about you. All other information collected up to the time of your withdrawal will be kept.

If you choose not to take part in the study, your surgeon will discuss the available treatment options with you.

**3. What are the possible benefits of taking part?**

With your help, this study will inform which treatment is the best for people suffering with this potentially life-changing fracture. You will not be benefited by this study but your contribution will help us develop and guide the future treatment for this injury and help patients in future.

**4. What are the possible risks?**

As reverse dynamization is a new treatment being tested in this study, there is the chance that it will result in the same, or worse outcomes, as compared to the routine standard of care which is the rigid frame fixation.

Both treatments require the same operation, and therefore surgical risks are similar for both treatment groups. Your surgeon and physiotherapist are experienced in the treatments provided and will do all they can to reduce risk. Your surgeon will be able to discuss the risks of the procedure in depth.

The standard risks for any tibial fractures are pain, infection (<3%), delayed / non union (< 5%), malunion (<5%). Other risks from having surgery are blood clots, and damage to adjacent structures such as blood vessels, nerves or tendons. Some of these can cause serious or long-lasting problems.

During your treatment you will require X-ray scans. All x rays are standard to assess the bone healing. Patients undergoing the variable reverse dynamization treatment may have 1 extra x-ray as mentioned previously.

X-ray scans do emit radiation. Radiation can cause damage to cells in the body which can lead to changes such as cancer. However, we are all exposed to natural background radiation every day of our lives from the sun, the food we eat, overseas flights we take and the ground. Including the 1 additional x-ray to normal practice, the total amount of x-rays given in this trial is equivalent to 1 month’s normal background radiation, which is extremely low risk for causing cancer.

**5. More information**

**What happens if there is a problem?**
If you have any concerns, you should speak to your surgeon or one of the researchers who can answer your questions (contact details at the end of this document).

If you are harmed due to someone’s negligence, you may have grounds for legal action and your rights are not affected by participating in the study.

If you wish to make a complaint, you can do this through the usual NHS procedures by contacting a Patient Advice and Liaison Services (PALS) officer (see contact details at the end of this information sheet).

If you become distressed during the research – we would encourage you to speak to the research team, so that they may attempt to help. Again you are reminded that you are free to withdraw consent /withdraw from the trial at any time, and even so you would still have access to the team that will care for their orthopaedic health. For distress specifically related to problems with mental health you would be supported to access usual healthcare pathways such as your general practitioner. The Patient Advice and Liaison Services team can also offer confidential advice and support, and may be able to offer help even if it isn’t regarding a specific complaint.

**Will my taking part be kept confidential?**
We would inform your GP/any doctor/nurse that may be treating you, that you are part of this study, and if necessary, ask for your updated contact details.

Any information that we have about you will be held securely at Hull University teaching hospitals or an alternative secure location. You will be given a participant ID number, which will be used to identify you on all trial forms and questionnaires. Information will be kept strictly confidential and will be held in line with appropriate legal frameworks.

Only the research team will have access to identifiable information, and anyone who does so will have a duty of confidentiality to you. If you agree to us sending a text message, your phone number will be stored on a secure system at the University of Hull. Text messages may be sent using a secure service managed by a third-party organisation. The University of Hull and third-party organisation will not use your mobile number for any other purposes and your information will not be shared with anyone else.

At the end of the study, the data collected from you will be securely archived for a minimum of 10 years. Confidential destruction will then be arranged.

### What will happen to the results of the study? After the study has concluded and the data has been evaluated, it will be published in medical journals and presented at conferences. You will not be identified in any reports. You may receive a summary of our findings if you wish. How will we use information about you?

We will need to use information from your medical records for this research project. This information will include your NHS number, name, contact details.  People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

### What are your choices about how your information is used?

* You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
* If you choose to stop taking part in the study, we would like to continue collecting information about your health. If you do not want this to happen, tell us and we will stop.
* We need to manage your records in specific ways for the research to be reliable. This means that we won’t be able to let you see or change the data we hold about you.

You can find out more about how we use your information at [www.hra.nhs.uk/information-about-patients/](https://www.hra.nhs.uk/information-about-patients/) or by asking one of the research team.

**How is the study organised?**
The study is sponsored by the Research & Development department in Hull & East Yorkshire Hospitals NHS Trust who will manage the study and quality assure trial processes.

This research project has been approved Research Ethics Committee to protect your interests.

Your treating clinician will not receive payments for their involvement in the study. Participation in this study should also not cost you anything.

**6. How to contact us**

If you need any further information, please contact us:

Chief Investigator: **Mr Hemant Kumar Sharma**
*Email: h.sharma@hull.ac.uk*, *Telephone: 01482674157*

Trial Coordinator: Matthew Marples
*Email: Matthew.marples@nhs.net*

Principle Investigator for each site:

James Cook University Hospital: **Mr David Ferguson**
*Email: David.ferguson5@nhs.net Telephone:*

Leeds General Infirmary: **Mr Paul Harwood***Email paulharwood@nhs.net Telephone:*

Northern General Hospital: **Jonathan McGregor-Riley**
*Email jcmriley@btinternet.com Telephone:*

Other investigators:
Research Nurse Hull: **Kim Dearnley.**
*Office: 01482 674771, Email: kim.dearnley@hey.nhs.uk.*

If you would like independent advice about whether or not to take part, please contact the Patient Advice and Liaison Service (PALS): pals.mailbox@hey.nhs.uk or 01482623065.

You can find independent information on research in general by contacting INVOLVE, the national advisory group of the National Institute for Health Research (telephone: 02380 651088, Email: admin@invo.org.uk, website: [www.invo.org.uk](http://www.invo.org.uk)).

Thank you for reading this information sheet and for taking the time to consider taking part in this study.