Treatment of Toddlers fractures: A multicentre non-inferiority RCT of observation or immobilisation

Parent/Guardian Information Sheet

You and your child are being invited to take part in a research study. Before you decide if you would like to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with a member of the study team at your hospital if you wish.

An overview of this information is also available in an animation video, which can be found here: www.tots-study.co.uk

In this document:

Part 1: tells you the purpose of this study and what will happen if you take part.

Part 2: gives you more detailed information about the study.

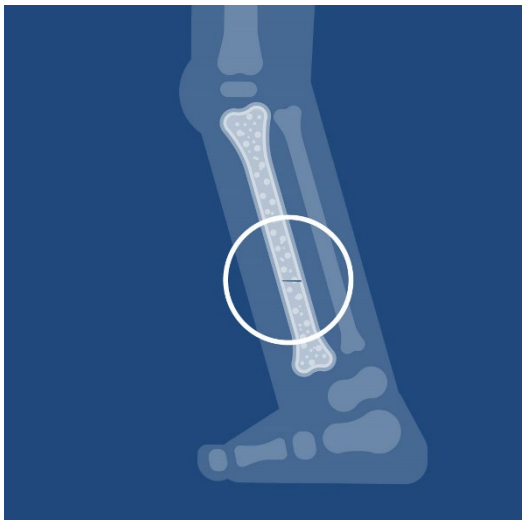
Please ask us if there is anything is not clear, or if you would like more information.

Part 1: What is the purpose of the study, and what will happen if I take part?

1. What is the purpose of the ToTs study?

When young children fall or twist their leg, they can get a type of injury referred to as a "toddler's fracture":

- This is a common minor injury which happens in the shin bone (tibia).
- Your child may feel pain, or not want to put weight on the injured leg.
- These injuries usually heal very well naturally because the bone in this age group has a thick surrounding layer called the periosteum.



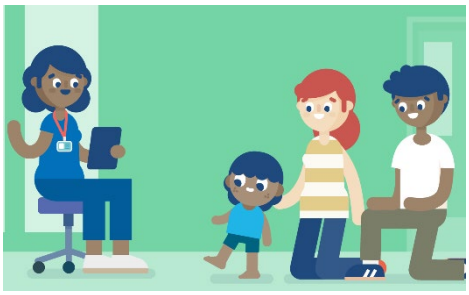
Sometimes, these fractures are treated by putting the leg in a cast or special boot to keep it still (immobilise it).

However, casts are not used in many hospitals and they are often managed with pain relief such as paracetamol as needed. Not casting may encourage the child to walk faster and prevents possible issues caused by casts such as ankle stiffness, pressure sores or skin issues.

Research suggests both methods might work equally well. However, there have been no large studies to confirm this. We are therefore running a large research study to compare both methods. We are aiming to include 494 children in this study.

2. Why has my child been asked to take part?

You have been invited to give permission for your child to take part in this study, as your doctor or nurse suspects they may have a toddler's fracture of their leg. This may have been confirmed by x-ray, but x-rays do not always clearly show a toddler's fracture.



3. Does my child have to take part?

No. Taking part in this research is always a choice. If you decide your child will not take part in the study, their care will not be affected. If you do decide that you would like your child to take part, you will be asked to complete a consent form on your child's behalf. You should ask any questions you like before you complete consent. If you wish, you do not need to make a decision straight away. You can instead revisit this at a next clinical contact, either in person or remotely, within three days.

You are free to change your mind and withdraw from the study at any time should you wish to do so.

Whether or not you decide to take part in the study, your child's doctor will discuss standard treatment options with you which will not be influenced by your decision whether to take part in the study or not.

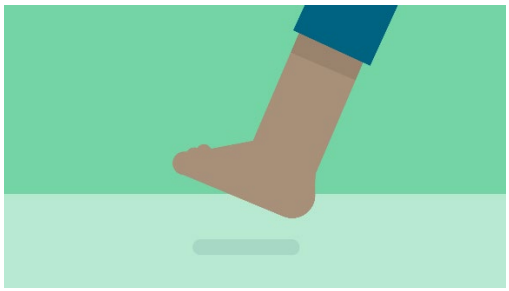
4. What will taking part involve?

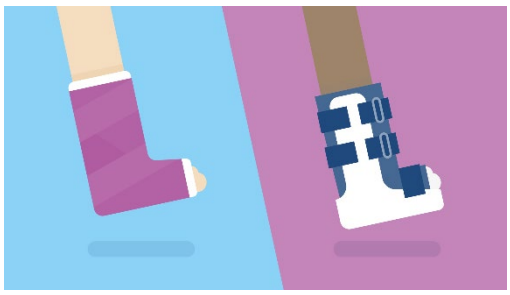
This study does not require any additional visits to hospital. It only requires completion of four short questionnaires over the next month. If you have any concerns you should contact your child's doctor or nurse, as these questionnaires will not be monitored.

If you would like your child to take part in the ToTs Study, and they meet all criteria to take part, your doctor or nurse will ask you to complete a simple questionnaire which asks you five questions to get an idea of their pain.

Following this, your doctor or nurse will use a computer to fairly choose between the two treatments for your child:

1. No cast ***OR*** **2. A cast/boot on the leg**





You, your child and the doctors or nurses will not be able to choose which group your child is placed in. You and your child will be told the treatment straight away and then given a cast/boot/bandage if required, as well as advice on this treatment.

After you have left the hospital, you will be asked to complete some more questionnaires at the following times (calculated based on when the computer system decided your child's treatment):

- 3 days
- 7 days
- 28 days

These questionnaires will include the same ones you answer at the start, as well as a few more questions including some about your child's mobility and any pain medication they have received, to help us understand how your child is recovering as well as your satisfaction with the treatment. We estimate that these should take approximately 10-20 minutes to complete.

You will be asked if you are happy to complete these online via a link sent to your email. If not, you can take away paper forms to return in a pre-paid envelope. If you are happy to leave your mobile phone number, we will send you text reminders to help you to complete the questionnaires. This study has been designed with short questionnaires to reduce the time taken for you to complete them. If possible, the same parent/guardian should complete the questionnaires each time.

After 28 days have passed, you will not be asked to do anything else for the study. The study team at your hospital will look at your child's medical notes to record whether they have had any more hospital or GP attendances related to the injury and what happened at these visits.

Your child's General Practitioner will be informed that they are taking part in the study.

5. What are the possible benefits of taking part?

If your child takes part in this study, they (and you) will be contributing to important research that will inform treatment choices for other children with a toddler's fracture in the future.

As a thank you for completing all questionnaires, you will be entered into a prize draw to win a £50 Love2Shop shopping voucher. Everyone taking part in the study will be entered, once all of the required questionnaires have been completed (at 3 days, 7 days and 28 days). These prize draws will take place for every 50 people who complete the questionnaires.

6. What are the possible disadvantages and risks of taking part?

If your child was not taking part in the study, they still may or may not have been offered a cast/boot, depending on what your doctor prefers. There are advantages and disadvantages of either way of treating the toddler's fracture.

- Using a cast or boot helps to keep the leg still, and there is a possibility that this reduces pain and protects the injury from further trauma, compared to not wearing a cast.
- However, there are also downsides to using a cast or boot.
- They sometimes cause skin sores and discomfort from rubbing, make the ankle and knee joints stiff, and may delay recovery by limiting movement.
- Being in a cast or boot can also cause more impact to you and your child's daily activities, and require more hospital visits for assessment and removal.

7. What happens when the study ends?

You and your child will be in the study until 28 days after you agree to take part. Your child will still be looked after by their doctors and nurses throughout. Although your involvement in the study will have ended after 28 days, other children may still be involved in the study. When the whole study ends:

- We will review all the information to see how toddler's fractures can be managed better in the future.
- We will keep you updated with study progress, and share the results of the study with you, if you wish.
- Anonymised results of the study will also be published on a freely accessible database and in scientific journals, and may be presented at clinical and academic conferences.
- The results will be used to inform treatment of toddler's Fractures in the future in the NHS and other countries.

8. Contact Details

If you have any questions about the information in this leaflet, or anything else to do with this study, please speak to your child's nurse or doctor, or local research team.

There are more details about the study available online at www.tots-study.co.uk.

This completes Part 1.

If the information in Part 1 has interested you and you are considering participating, please read the additional information in Part 2 before making any decision.
Part 2 contains details about who is organising and funding the study, how your information will be used, and what to do if you have a problem or complaint.

Part 2

1. Who is organising and funding the study?

The study has been designed by Paediatric Orthopaedic Surgeons and Emergency Physicians, along with patient representatives and researchers. The research is organised by the University of Sheffield Clinical Trials Research Unit on behalf of Sheffield Children's NHS Foundation Trust (the Sponsor). This project is funded by the NIHR Health Technology Assessment (HTA) Programme (project number NIHR165783).

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been reviewed and approved by West of Scotland Research Ethics Committee 5.

2. How will we use information about you?

We will need to use information from your child, and your child's medical records, for this research project. This information will include:

- Your child's NHS number
- Your child's name
- Your child's Date of Birth
- Your 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 child's name or your contact details. Your data will have a code number instead.

Sheffield Children's Hospital are responsible for looking after your information. We will share your information related to this research project with the following types of organisations:

- The hospital you are receiving care from
- The University of Sheffield (as they organise the research)
- Anonymised results of the study may be published on an online database, in scientific journals, and at conferences.

We will keep all information about you safe and secure by:

- Information collected about you for the study will be stored on a secure database at the University of Sheffield. Any paper documents will be stored within a locked cabinet in a locked office.
- Information collected as part of the study will only be accessible by those involved in the running of the study.
- All of these staff are trained in data protection (GDPR).

3. International Transfers

Your child's data will not be shared outside the UK.

4. How will we use information about you after the study ends?

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.

We will keep your study data for a maximum of 10 years. The study data will then be fully anonymised and securely archived or destroyed.

5. What are your choices about how your information is used?

You can stop your child being part of the study at any time, without giving a reason, but we will keep information about your child that we already have.

If you choose for your child to stop taking part in the study, we would like to continue collecting information about your child's health from their hospital. If you do not want this to happen, tell us and we will stop.

You have the right to ask us to access, remove, change or delete data we hold about your child for the purposes of the study. You can also object to our processing of your child's data. We might not always be able to do this if it means we cannot use your child's data to do the research. If so, we will tell you why we cannot do this.

If you agree to take part in this study, you will have the option to take part in future research using your child's data saved from this study.

6. Where can you find out more about how your information is used?

You can find out more about how we use your information:

- our leaflet: www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to tots@sheffield.ac.uk, or
- by ringing us on 0114 222 0746

7. What if there is a problem?

Remember that if you have any concerns about your child you should contact your child's doctor or nurse at your hospital, as the questionnaires you submit will not be monitored.

If you have a concern about any aspect of the study:

- You should ask to speak to the study team at your hospital, who will do their best to answer any questions you may have. You will have been provided with their contact details.
- If you remain unhappy and wish to make a complaint, you can do this through the NHS Complaints Procedure, and the details for your local PALS team are available on the study website.

In the event that something does go wrong, and this is due to someone's negligence then you may have grounds for legal action for compensation against your treating hospital, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

If you wish to make a report of a concern or incident relating to potential exploitation, abuse or harm resulting from your involvement in this project, please contact the project's Designated Safeguarding Contact though your local PALS team (details on the study website). If the concern or incident relates to the Designated Safeguarding Contact, or if you feel a report you have made to this Contact has not been handled in a satisfactory way, please contact the Sponsor safeguarding team at Sheffield Children's Hospital on 0114 226 7803 and/or the University's Research Ethics & Integrity Manager (Lindsay Unwin; l.v.unwin@sheffield.ac.uk).

Thank you for reading this document and for considering taking part in the study. If you decide to take part, this will be helpful to many families in the future.