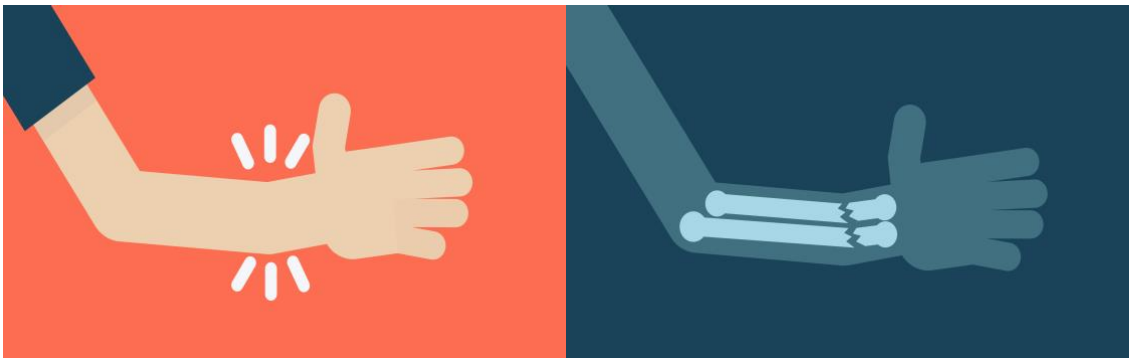
Parent/Guardian Information Sheet

WHAT IS CRAFFT?

The CRAFFT study is trying to find out the best way to treat children who have broken their arm at the wrist, and the bones have moved out of place.



The study is comparing the two most common treatments used throughout the UK:

The first treatment is to put the arm in a plaster cast for four to six weeks, allowing the broken bones to heal, and grow back to the right position naturally. With this treatment the wrist might not look fully straight for a few months. However, there is evidence that children's bones will naturally grow straight up to 11 years old. There are risks involved with this treatment: the injured arm may not look the same as the other arm while it heals; healing may take longer and; in rare cases, if the arm does not grow straight an operation may be required.

The second treatment is to put the bones back into the right position - this requires a procedure or operation. To put the bones back, your child is sedated in the Emergency Department or has a general anaesthetic in an operating theatre, so they can't feel anything with either sedation or anaesthetic. Sometimes the doctors may have to make a cut in the arm to insert plates or wires to hold the bones in position, which would need to be removed at a later stage. After the procedure the arm is put in a plaster cast for four to six weeks. There are risks involved with this treatment: the bone may still move out of place and in those who have an operation an infection may sometimes occur.

The clinical team at your hospital has a lot of experience with providing both of these treatments.

In the CRAFFT study, half the children will be treated in a cast, allowing the arm to straighten naturally, and half will have their broken bone treated with a procedure to straighten the arm. To make things fair, the treatment will be decided using a computer, in a process called randomisation.

You are free to decide whether or not you wish for your child to take part. Your decision will not affect the level of care your child will receive.

1) IMPORTANT THINGS THAT YOU NEED TO KNOW

- Your child has been diagnosed with a break of the forearm bone near the wrist. This is a common injury that with either treatment normally heals well over time.
- Doctors are not sure whether it is best to:
    I. Treat the broken bones in a plaster cast, allowing the bones to grow back into the right position naturally.
    II. Put the bones back in the right position. Your child will need a general anaesthetic or sedation to straighten the broken bone, which will then be held in place with a plaster cast and, if necessary, a metal plate or wires.
- You will be asked to complete some questions with your child about their pain, activities and feelings. These questions will be asked when you decide to take part, and on four further occasions over the next 12 months. To assess the longer-term effects of the injury, we will also ask the same questions at the two and three year anniversary of the injury.
- You may be invited to take part in a sub-study exploring your experience of your child's injury, its impact on their daily life and your experience of being asked to participate this study.
- A link to the questions will be sent to your mobile phone or e-mail address and should take no more than 10 minutes to complete. We are able to send you a £10 gift voucher at 12 months after joining the study to reimburse you for the costs of your internet data.

2) WHAT TREATMENT WILL MY CHILD RECEIVE?

We will involve at least 750 children from across the UK, with the same injury as your child.

This is a randomised study, which means that the treatment given to your child will be chosen by a computer. The computer will fairly divide the participating children between the treatments. By looking at everyone's care together, we can then improve our understanding about the best way to treat these injuries in the future.

3) WILL THERE BE EXTRA TESTS?

No. This study asks you and/or your child some extra questions, and makes use of the routine information that your doctor collects, but we will do no additional tests.

4) ARE THERE ANY RISKS IN TAKING PART?

Both treatment options are currently being used to treat this type of injury and each carries a different set of risks, which are explained above. There are no additional risks to your child from taking part in the CRAFFT study.

Children in both groups are at risk of irritation related to the cast, pressure areas and a condition related to muscle swelling called compartment syndrome, though the risk is likely to be slightly greater in the group who get a procedure or operation.

5) WHAT DOES THE STUDY INVOLVE?

If you decide you would like your child to take part, a member of the study team will ask you to complete:

1. A consent form. Older children will also be asked to complete an assent form whereby the child also gives their permission to take part.
2. A contact information form so we can contact you about your child's recovery.
3. A questionnaire about pain, activities and feelings, and very brief information about your child's medical history. This should take about 5-10 minutes.

Basic information (such as your child's age and which hospital you are in) will be entered onto a computer, which will decide which treatment your child will receive.

During your child's recovery, we will contact you by text message and/or email (at 4pm and approaching bedtime at 7pm) after six weeks, three months, six months, 12 months, and then annually until three years after joining the study. We will ask questions about pain, activities, feelings, school attendance and any costs that you may have incurred in relation to this injury (i.e. days absent from work etc). It is important that you try and complete the questionnaires with your child as soon as possible after they are received. We will send you an advance notification that a questionnaire will be on its way and reminders if they are not completed. We will use a small image in any e-mails that we send to you to let us know when you have opened the e-mail. We will use this information so that we can improve the timing of sending you and other participants information about your participation in this study.

If the questionnaire is not completed, we will send you a reminder after a few days (by phone, text or e-mail based on your preference). If it is not completed after one week, or if we have any queries about the information you have already provided, we may contact you to ask the questions over the telephone or by email/text. We are able to offer a £10 gift voucher 12 months after joining the study as compensation for any costs (i.e. mobile phone data) incurred whilst completing the questionnaires.

Any routine images of the wrist taken during your child's recovery will be collected at 12 months and three years, where available.

Your child will be given a unique study identification number which will be used for all of the information we collect from you about your child. This information will be transferred to, and stored at, The University of Oxford, using a secure, encrypted web-based system.

If you prefer for your child not to be part of this study, this will not change the level of care they will receive. You can change your mind about participating at any time and can contact the research team using the electronic forms that you receive. Once the study is finished, the results will be available to you online at our study website (www.CRAFFTstudy.org). All results will be anonymised so no one can identify you or your child from the results.

6) WHO IS INVOLVED WITH THE STUDY?

The study is funded by the Department of Health and is the work of Children's Emergency Doctors and Bone Specialists across the UK, with research support from The University of Oxford. The University of Oxford is the sponsor for the study and the day to day running of the study is being completed by Oxford Trauma, a research group of the Nuffield Department of Rheumatology, Orthopaedics and Musculoskelatal Sciences.

The research team is qualified to do this study because they have all the specialties and skills needed. The team has a lot of experience in caring for children and young people with injuries and are active in health research. Parents and children have been involved in the development of this study, and are involved in the management.

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given a favourable opinion by the West Midlands - Black Country Research Ethics Committee.

7) HOW WILL WE USE INFORMATION ABOUT YOU AND YOUR CHILD?

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

- you and your child's name,
- your child's NHS number and date of birth

- your contact details
- secondary contact details.

Data protection regulation requires that we tell you about the legal basis for processing information about you and your child. In the case of research, this is "a task in the public interest" The University of Oxford will act as the data controller. This means that the university are responsible for looking after your and your child's information and using it properly.

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.

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 information about you safe and secure for at least 17 years after completion of the study, or until the youngest child reaches 21 years old (whichever is later) as per the University requirements for studies that include children.

Your treating hospital will collect and hold information about you, your child and/or your child's medical records for this research study in accordance with our instructions.

We will keep identifiable information (contact details) about you for a minimum of 12 months after the study has finished.

8) 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 child's health from your hospital or your GP. If you do not want this to happen, please tell us and we will stop.

We need to manage your child's 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 them.

If you agree for your child to take part in this study, the information collected about your child may be used to support other research in the future, and may be shared anonymously with other researchers.

9) WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED?

- Through the Health Research Authority - www.hra.nhs.uk/information-about-patients/
- At the CRAFFT website - www.CRAFFTstudy.org
- By asking one of the research team
- By sending an email to CRAFFT@ndorms.ox.ac.uk
- By calling us on 01865 228929

10) WHAT IF SOMETHING GOES WRONG?

The University of Oxford has appropriate insurance in place in the unlikely event that your child suffers any harm as a direct consequence of their participation in this trial. NHS indemnity covers any other clinical treatment with which you are provided.

If you have a complaint or you have a concern about any aspect of the way you have been treated during this study, you should. contact Professor Daniel Perry who is the overall study lead on 01865 228929 or

email daniel.perry@ndorms.ox.ac.uk or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480 or the head of CTRG email: ctrg@admin.ox.ac.uk

If you remain unhappy and wish to complain formally, you can do this by contacting NHS Complaints. Ask your treating hospital for the contact details or visit https://www.nhs.uk/using-the-nhs/about-the-nhs/how-to-complain-to-the-nhs/