CRAFFT – Children's Radius Acute Fracture Fixation Trial.

Summary 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 bone to heal, and then grow back into 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. The risks for this treatment are that 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. 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, based on how many children are in the study, 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.

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. We will do no additional tests.

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 greater in the group who get a procedure or operation.

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.
4. 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.

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 6 weeks, 3 months, 6 months, 12 months, and then annually until 3 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. If the questionnaire is not completed, we may contact you in the following days. 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.

HOW IS YOUR INFORMATION USED?

In this research study we will use information from you, your child and their 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**.** We will make sure no-one can work out who you are from the reports we write.

The information pack tells you more about this, please visit the study website at www.CRAFFTstudy.org. 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.

We may disclose your personal data to our third-party service providers to carry out activities specifically for the purpose of this research study and as explained in this information sheet for example text messaging service providers/companies to send study-related text messages to you. Any third-party service providers are required to take appropriate security measures to protect your personal data in line with University of Oxford policies. We do not allow our third-party service providers to use your personal data for their own purposes, but rather to only process your personal data for specified purposes and in accordance with our instructions.

If you have a complaint or you have a concern about the way you have been treated during this study, you should contact Professor Daniel Perry who is the overall study lead on 01865 227902 or email daniel.perry@ndorms.ox.ac.uk, or you may contact the University of Oxford Research Governance, Ethics & Assurance (RGEA) office on 01865 616480 or email: RGEA.complaints@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/