FLexor repAir and REhabilitation (FLARE) Trial

Summary Patient Information Sheet

Dear patient,

We invite you to take part in our study.

Your hospital is working with other NHS hospitals and the University of York on a study. The study compares two types of surgical repair for patients who have a cut through the flexor tendons that bend the middle knuckle and the tip of their finger. Both surgeries are already used within the NHS.

We are looking for 310 patients around the country to take part in this study. Will you be one of them?

The decision is yours.

Why have I been invited to take part?
You have an injured finger and might have cut both flexor tendons in your finger.

What do flexor tendons do?
Each finger has two flexor tendons. They are rope like structures connecting the muscles in your forearm to the bones of your fingers. One tendon goes to the fingertip and the other half way down the finger (see Figure 1). They bend your fingers into the palm.

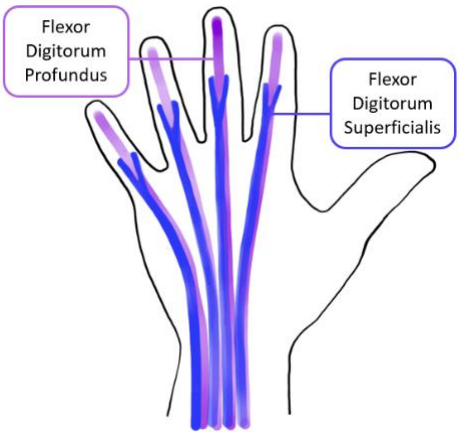

Figure 1: Flexor Digitorum Profundus and Flexor Digitorum Superficialis

How are flexor tendon injuries treated?
Surgeons usually offer to repair the tendons with stitches. This gets the finger moving again.

Why is the FLARE trial needed?
If both tendons are completely cut, surgeons and patients are unsure whether the tendon to the tip of the finger should be repaired alone or along with the other tendon.

Why the uncertainty?
Repairing both tendons might give more strength but has a higher chance of the tendons getting stuck, giving worse movement.
Repairing just the tendon to the fingertip alone might give better movement but less power.

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What is involved in the FLARE trial?

We are recruiting 310 patients. Half will have just the tendon to the fingertip repaired. Half will have both tendons repaired. If you choose to take part in the study;

1. Through a computer programme you will be allocated to one of the surgical treatments (either to repair of one tendon or both).
2. You will not know which treatment has been completed until 6 months after your surgery.
3. You will be asked to attend routine clinic visits, the same as the patients who are not taking part in the study. Study information will be collected at your routine appointments completed within one week of your surgery and then at six weeks and three months after your surgery.
4. A questionnaire will be sent to you 6 weeks, 3 months and 6 months after surgery either by post, email or telephone.
5. The 6 month questionnaire is the last activity you will be asked to complete, unless you choose to agree to be contacted for the study interview.
6. Following end of your participation at 6 months you will receive £10 as a thank you, and find out which surgical repair you received.

Once all of the 310 patients have completed the study, we will then compare the outcome of both groups to see if there is a difference. This will help future patients and surgeons make decisions about their treatment.

Do I have to take part?

You do not have to take part. Involvement in the FLARE Trial is voluntary. If you choose to take part, you can still stop at any time. If you choose not to take part, you will still receive the very best treatment available.

Contact details

You can ask your treating surgeon or research staff any questions you may have about the study.

If you are interested in finding out more, we will provide you with a more detailed participant information sheet. This gives additional information about what is involved in taking part in this research, including how your medical information will be used and your privacy protected. We will also discuss the study with you in person to ensure everything is clear and to answer any questions that you may have.

For alternative formats of this information, please go to the FLARE Trial website: www.flaretrial.com.

Thank you for reading this information sheet and for considering whether to take part.

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