DISC: Dupuytren's Interventions Surgery vs Collagenase Trial: Participant Information Sheet

We would like to invite you to take part in a research study

Before you decide whether to take part, it is important for you to understand why the research is being done, and what taking part will involve.

Please read the following information carefully and discuss this with anyone else you wish such as a friend, nurse, doctor or relative. You may also wish to look at the DISC Infographic given to you with this information sheet. It provides a summary of why this research is being done.

We are very happy to provide more information if anything is unclear and can be contacted using the details at the end of the leaflet. Please take as much time as you need to decide whether you want to take part.

The DISC Trial in brief

We are running this study to find out how best to treat Dupuytren's Contracture. We want to find out if collagenase injections are as good and as safe as surgery for treating this condition.

We are inviting people in your area who have Dupuytren's Contracture to take part in this research study. In the study, some people will receive an injection of Collagenase whilst others will receive surgery. The treatment people receive will be selected by chance.

If you take part, we will ask you to fill in some questionnaires over the next two years. We will also monitor your Dupuytren's Contracture before and after treatment.

The study is being run across the United Kingdom. <INSERT SITE NAME> are running this study in your area. In total, the study will run from May 2017 until April 2022.

The study is being run by the University Hospitals of Leicester and the University of York. This study is funded by the National Institute for Health Research Health Technology Assessment Programme (15/102/04).

Inside this Leaflet:

More detailed information about the study can be found inside this leaflet

This project was funded by the National Institute for Health Research Health Technology Assessment Programme (project number 15/102/04). The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.

What is the purpose of this study?

Dupuytren's Contracture is a common problem affecting the hand. The condition is caused by fibrous tissue, which forces the finger to bend down into the palm.

The common treatment for this condition is surgery to remove the tissue and straighten the bent finger. A different and new treatment is a Collagenase injection, which softens the fibrous tissue. This is given in clinic, and is followed up in clinic a few days later where the finger is moved to help to straighten it. Both treatments are offered on the NHS in England and are also used in the USA and Europe.

We are running this study as both treatments are currently used in the NHS, but we are unsure if the injection is as good and as safe as surgery at correcting the bent finger. We are also unsure if the correction continues in the long term and if the complication rates are similar. To find the answer to this question, the DISC Trial will recruit 710 patients with Dupuytren's Contracture.

Why have I been chosen?

You have been chosen because you have Dupuytren's Contracture and are awaiting treatment.

You would not be able to take part in the study if you:

- Have had surgery or collagenase injections on the same finger for Dupuytren's Contracture
- Have pre-existing conditions affecting hand movement, function or pain (e.g. Arthritis, infection, stiffness)
- Have a condition which prevents the use of Collagenase
- Are pregnant or breastfeeding
- Have taken part in another research study in the last 12 weeks

Do I have to take part?

No, taking part is voluntary. It is up to you to decide whether or not you wish to be involved. If you do decide to take part you will be given this information sheet to keep and you will be asked to sign a consent form to confirm your decision.

If you agree to take part but later change your mind, you can leave the study at any time without giving a reason and your future care and treatment will not be affected.

If you leave the study we will still keep your records relating to the treatment given to you as this is valuable to the study. If you do not want us to keep this information please let the study team know.

What will happen if I take part?

This study will take approximately 5 years to complete but if you take part we will only ask for your help for 2 years.

<u>Baseline Visit</u>

If you are suitable for the study, and happy to take part, we will ask you to complete a study consent form. You will be given a copy to keep and a copy will be sent to York Trials Unit for storage. We will assess your hand, take a photograph and ask you some questions about your condition and your general health. This visit may be completed by telephone or video, or in person within UK government COVID-19 pandemic related guidelines. If conducted by telephone, we will ask you to take photographs of your hand (if you are able to do so).

You will then be randomly allocated to receive the injection or surgery. You will have an equal chance of getting either treatment. If you receive the injection you may need to attend 2 clinic visits for treatment.

Before you receive your intervention, we will re-assess your hand and will ask you to complete a short questionnaire about your hand health.

What will happen if I take part?

Follow Up Visits

After treatment, you will be asked to complete two short questionnaires by post. We will ask you to complete another 4 visits where we will assess your hand, ask some questions about your hand function, general health and take a photograph of your hand. Each visit will last about 1 hour. This visit may be completed by telephone or video, or in person within UK government COVID-19 pandemic related guidelines. If conducted by telephone, we will ask you to take a photograph of your hand (if you are able to do so). We will also ask you about any medical visits you have had since your last visit – we will provide you with a visit diary to complete to help you to remember the visits you have had and the reasons for them.

To thank you for your help we will reimburse you with £40 at the 1 and 2 year follow up visits. You will continue to see your consultant for treatment and review. When the research ends, you will return to standard NHS care.

Study information and your medical records, may be viewed by individuals from the study team, the Sponsor, the Research Ethics Committee, the NHS Trust or UK regulatory authorities. These organisations may do this to ensure the study is carried out to the highest standards. Anyone looking at this information will have a duty of confidentiality to you as a research participant. By signing the consent form, you agree to this access for this study and any further research conducted in relation to it, even if you withdraw from this study.

You will also have the option of taking part in a further element of the DISC Trial, the photography sub-study. If you do not wish to take part in the sub study, this will not affect your participation in the main trial.

Photography sub study

We would like to find out if we can measure finger extension from photographs rather than from an assessment in clinic. We will ask you to take photographs at baseline and at each of the follow up time points or until the research team tell you otherwise for any reason. We will provide you with guidance on taking the photographs and will you will be asked to email or send the pictures to the study team. You can also view a video about this at: www.york.ac.uk/healthsciences/research/trials/research/trials/disc/. Your images will be stored securely and may be used anonymously for publications or presentations.

If you agree to take part in this sub study you will be asked to sign another consent form and you will be given a copy to keep. A copy will be sent to York Trials Unit for storage. You do not have to consent to this sub study and if you do not take part this will not affect your ability to take part in the main trial.

Future research

The information collected in the main trial and sub studies may be used to support other research in the future. Any information shared will be done so anonymously.

What drug or procedure is being tested?

There are no experimental drugs or treatments involved in this study. Collagenase and surgery can be used in the treatment of Dupuytren's Contracture in the UK.

What are the benefits of taking part?

We hope your condition will improve with either treatment. The known benefits are described in the Infographic. The information from this study may help us to treat people with Dupuytren's Contracture more effectively in the future.

What are disadvantages and risks of taking part?

We do not expect that being in this study will harm you or limit your care in any way. Your care is of utmost importance to us, and we will ensure you are treated in a hospital that has all appropriate COVID-19 related safety measures in place.

As with any treatment, there are always potential risks, these are described in the DISC Infographic and detailed below. You should discuss these risks with your GP or consultant.

Collagenase Injection

Collagenase is approved for use in Dupuytren's Contracture in the UK. Common side effects include injection site swelling, bruising and pain. These often subside within 1 – 2 weeks of the injection.

The injection may also affect your ability to drive or use machinery as it may cause dizziness, headaches, tingling sensation or reduced sense of touch. You should therefore avoid driving or using machines until these symptoms have passed.

Very rarely, allergic reactions and tendon rupture may occur. If you have swelling in your throat, difficulty breathing or trouble bending the finger (once any swelling has reduced) please tell the study doctor or nurse straight away.

Surgery

Surgery is the common treatment for Dupuytren's Contracture. Common side effects of surgery may be experienced such as pain, bruising, swelling or infection.

Surgery will require an anaesthetic. Common, short-term side effects include dizziness, headaches and numbness.

What happens if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can obtain advice from your local Patient Advice and Liaison Service. Contact details are provided at the end of this leaflet.

If something does go wrong and you are harmed during the research, NHS negligence procedures apply as there are no special compensation arrangements for this study. If you are harmed due to someone's negligence, then you may have grounds for legal action but you may have to pay your legal fees.

In an emergency, you should contact your research doctor or nurse. The name of the contact nurse and telephone number is provided at the end of this leaflet.

What happens when the research stops?

When the research study ends, you will return to standard NHS care either with your GP or consultant.

What if new information becomes available?

Sometimes during a clinical trial, new information regarding the treatments being studied becomes available. If this happens, your nurse or doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw from the study, your care will continue within the NHS. If you decide to continue, then you will be asked to sign an updated consent form.

What happens if I no longer wish to take part in the study?

You can leave the study at any time without having any further assessments.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways to ensure the research is reliable and accurate.

If you leave the study, we would like to use the information we have collected from you as this is valuable to the study. If you do not want us to use this information, you can let the study team know. If you do allow us to use the information we have collected, to safeguard your rights, we will use the minimum personally-identifiable information possible.

If you decide to leave the study, your care will continue in the NHS. A decision not to carry on with the study will not affect the quality of care you receive in any way.

Will taking part in this study be kept confidential?

If you take part we will tell your GP and any doctor or nurse who may be treating you.

Information collected from you during the research and from your health records will be held securely on paper or electronically at the study site and York Trials Unit, the site organising the research. Information will be kept strictly confidential and will be held in line with the Data Protection Act (2018).

Your name, address and telephone number will be stored securely at the University of York and the study site to allow us to contact you about study questionnaires, to make sure that relevant information about the study is recorded for your care, and to oversee the study quality. Your name will not be passed to anyone outside of the research team.

Individuals from University Hospitals of Leicester NHS Trust and regulatory organisations may look at your medical and research records to check the accuracy of this study.

The people who analyse the information will not be able to identify you and will not be able to find out your name, or contact details.

You will be given a participant ID number, which will be used as a code to identify you on all trial forms. This includes photographs of your hand and study questionnaires, which we will complete during the study. These will be sent and stored securely and will not include your name or any details about you on them. Your name will only appear on your consent form, which will be sent separately to any trial data collected.

Anonymised results from the study may be stored indefinitely for other health and care research in the future. Any identifying information will be kept strictly confidential, and access will be limited to the original study and database teams, and this will not be used to contact you, to affect your care or to make future decisions about services available to you.

Anyone who views the information we collect during the study, and your medical records, will have a duty of confidentiality to you as a research participant.

What will happen to the results of this study?

The results of the study will be made available to you once the trial has finished.

The results will be published in a medical journal and/or presented at a scientific conference. You will not be identified in any publication or presentation arising from this study.

Who is organising and funding the research?

The study is funded by the National Institute for Health Research (Reference: 15/102/04). Your nurse and doctor are not receiving any money for conducting this research.

The study is being coordinated by the University of York – York Trials Unit. The study is sponsored by the University Hospitals of Leicester NHS Trust.

We will be using information from you and/or your medical records in order to undertake this research and the sponsor will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Other collaborating institutions will also be processing your data and will keep identifiable information about you. You can find out more about how we use your information at: http://www.leicestershospitals.nhs.uk/aboutus/about-this-website/fair-processing-notice/

If you agree to take part in the trial, the University of York, and participating hospitals will keep information on you for a minimum of 25 years. If you agree to take part in the photography and/or qualitative sub study, University Hospitals of Leicester and the University of Nottingham will keep data on you for a minimum of 25 years respectively. Confidential destruction will then be arranged.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a research ethics committee. The Yorkshire & The Humber - Leeds West Research Ethics Committee have reviewed and approved this study.

How have patients and the public helped to design the study?

Service users have confirmed the importance of this research question, have reviewed the participant information sheet and other study documentation, and have advised on the best questionnaires to use in the study.

What do I do now?

Having read this information you may decide:

Yes, I would like to take part

If you are interested in taking part, please discuss this study with your consultant at your next appointment. If you decide to take part, you will be given a copy of this information sheet to keep and will be asked to sign a consent form to confirm your decision.

No, I do not wish to take part

If you do not wish to take part you do not need to do anything. Thank you for reading this information.

I am unsure and would like more information

If you do not understand anything on this information sheet or would like further information please contact the nurse on the telephone number provided.

Contact Details

You are encouraged to ask questions if you wish before, during and after your treatment. If you have any questions, please contact the study contacts below:

Research Nurse: [INSERT SITE CONTACT DETAILS INCLUDING OUT OF HOURS

Alternatively you can contact:
Study Coordinator: [INSERT CONTACT DETAILS]

If you would like to talk to someone else for general information and advice on taking part in research please contact:
[INSERT LOCAL PALS DETAILS]

Thank you for reading this information sheet and for considering taking part in this study.