Dupuytren's Interventions Surgery vs Collagenase

Confirmation of Eligibility Case Report Form

FOR STUDY INVESTIGATOR COMPLETION

Site ID: ☐☐

Participant Study Number: ☐☐☐☐

Participant Initials: ☐☐☐

Date form completed: ☐☐ / ☐☐ / ☐☐☐☐
day *month* *year*

University of York

NHS University Hospitals of Leicester NHS Trust

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Instructions for this questionnaire

This Case Report Form (CRF) must only be completed for patients who have been confirmed to be eligible for study participation based on information in the DISC Trial Screening For Eligibility Summary and who have consented to take part in the trial based on the DISC Written Consent form. The Screening Number pre-printed on the corresponding DISC Trial Screening for Eligibility Summary form should be entered as the Participant Study Number on the cover page of this CRF.

Informed consent must be obtained prior to any procedures being undertaken, including completion of this form.

This CRF may be completed by the principal investigator or a delegated member of staff listed on the DISC Trial Delegation Log.

The details written on this form and the eligibility of the patient must be confirmed by the PI or delegated medic (i.e. the Assessor), who must sign and date Section A-2 of this form and provide their Assessor ID.

Please complete all sections of this questionnaire using the spaces provided, and sign off when complete.

When complete, please remove the staple and take a photocopy of the completed CRF for site records.

Please do not re-staple original. Place the unstapled original in a “DISC business reply envelope” and send via post to York Trials Unit.

Section A – Consent and Eligibility
A-1 Consent

Informed Consent Process	
Date participant given Participant Information Sheet	Date: ☐☐ / ☐☐ / ☐☐☐☐ (day / month / year)
Date participant signed Written Consent Form	Date: ☐☐ / ☐☐ / ☐☐☐☐ (day / month / year) Version: v ☐
Date & Version Number of Participant Information Sheet consented to	Date: ☐☐ / ☐☐ / ☐☐☐☐ (day / month / year) Version: v ☐
Name of person taking Informed Consent	Name: ☐
A copy of the signed consent/ participant information sheet has been given to the participant	Yes ☐
A copy of the signed consent form/ participant information sheet has been filed in the medical notes	Yes ☐
A written or printed entry detailing the consent process and confirming eligibility has been made in the main body of the medical notes and signed by a delegated medic	Yes ☐

Signature of person completing page: ☐ Date *(dd/mm/yyyy)*: ☐☐ / ☐☐ / ☐☐☐☐ Assessor ID: ☐☐

A-2 Eligibility

Date of Eligibility Assessment ☐☐ / ☐☐ / ☐☐☐☐ *(dd/mm/yyyy)*

Inclusion Criteria	YES	NO
1. Male or female and aged 18 years or over	☐	☐
2. Presence of discrete, palpable, contracted cord involving the metacarpophalangeal joint and/or proximal interphalangeal joint of a finger	☐	☐
3. Degree of contracture ≥30 degrees in either joint i.e. patient cannot put the palm of the hand flat on a table (Hueston's Table top test)	☐	☐
4. Able to identify a predominant cord for treatment which would not require more than one Collagenase injection as treatment	☐	☐
5. Appropriate for limited fasciectomy surgery and Collagenase injection for Dupuytren's contracture (i.e. cords suitable for CCH and limited fasciectomy and not requiring skin grafting or PNF (e.g. discrete MCP cords in elderly))	☐	☐
6. Patient is willing and able to give informed consent for participation in the study	☐	☐

If any of the above criteria is answered NO, the subject is not eligible for the trial and must not be included in the study.

Exclusion Criteria	YES	NO
1. Severe contractures of both metacarpophalangeal joint and/or proximal interphalangeal joints (Tubiana Grade 4)	☐	☐
2. History of previous intervention for Dupuytren's contracture (e.g. surgery, Collagenase injection or needle fasciectomy) to the study reference digit.	☐	☐
3. History of any other pre-existing disorder of the hand causing significant restriction of movement and/or pain and affecting hand function e.g. post traumatic stiffness, stiffness due to other causes, infection, arthritis	☐	☐
4. Non-English speaking because of the need to complete multiple questionnaires which have not been validated in multiple languages	☐	☐
5. Resident in a location where attendance for follow up at one of the study recruiting centres will not be possible	☐	☐
6. Contraindicated for use of Collagenase including: • Hypersensitivity to: Collagenase, Sucrose, Ketorolac Trometamol, Hydrochloric acid, Calcium chloride dehydrate, Sodium chloride. • Diagnosis of a coagulation disorder	☐	☐
7. Any other significant disease or disorder (including autoimmune disorders) which, in the opinion of the Investigator, may put the participant at risk because of participation in the study, or may influence the result of the study, or the participant's ability to participate in the study	☐	☐
8. Participation in another research study involving an investigational product in the past 12 weeks	☐	☐
9. Female participants who report to be pregnant or breastfeeding	☐	☐

If any of the above criteria is answered YES, the subject is not eligible for the trial and must not be included in the study.

Signature of person completing page: Date *(dd/mm/yyyy)*: ☐☐ / ☐☐ / ☐☐☐☐ Assessor ID: ☐☐

The patient is eligible and can be included in the DISC Trial ☐ Yes ☐ No

Principal Investigator's (or delegated medic *) Name:

Principal Investigator's (or delegated medic *) Signature:

Assessor ID: | |

Date: | | / | | / | | | | |
day month year

*Must be reflected in the Delegation of Authority Log