***Supplemental Digital Content 2:***

**1.Consent Form**

**2.Research Participation Information Sheet**

**3. NICE information**

**4. Letter to GP**

***1. Consent Form***

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**Homerton University Hospital NHS Foundation Trust**

Physiotherapy Department

Homerton Row

London

E9 6SR

Tel: 020 8510 5751

Fax: 020 8510 7796

**RCT of Injection of Autologous Blood for Chronic Shoulder, Elbow and Knee Tendinopathy**

I agree to take part in this research which is to examine the use of autologous blood injection therapy in chronic tendinopathy □

The researcher has explained to my satisfaction the purpose of the study and the possible risks involved. □

I have had the principles and the procedure explained to me and I have also read the information sheet. I understand the principles and procedures fully. □

I am aware that I will be required to answer questions in the form of a questionnaire. □

I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the research team, regulatory authorities, or from the NHS Trust where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. □

I understand that I am free to withdraw from the study at any time, without giving a reason, and that this will not affect the treatment I receive. □

I have read the patient information sheet entitled, Understanding NICE Guidance: Treating tendon problems by injecting patients with their own blood. □

Name of Patient (please print) ……………………………………………………………

Signed ……………………………………………………………

Date ……………………………………………………………

Name of Researcher taking consent ...............................................................

Signed ...............................................................

Date ...............................................................

1 for patient 1 for researcher 1 to be kept with hospital notes

***2. Research Participant Information Sheet***

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**Study To Investigate The Effect Of Autologous Blood Injection In Patients With Chronic Shoulder, Elbow or Knee Tendinopathy**

Dear Sir / Madam,

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

**What is the purpose of the study?**

Tendinopathy – damage to a tendon, can commonly affect the shoulder, elbow and knee causing pain, dysfunction and weakness. Various treatments have been used for this including specific exercises, anti inflammatory medication and injections. New evidence suggests that autologous blood – one’s own blood can be injected into the site of the tendinopathy to promote healing and allow exercises to improve function.

The purpose of this study is to investigate the use of autologous blood in tendinopathies, it will be compared with normal saline which does no harm but is thought not to have any benefit either.

**Why have I been chosen?**

You have been chosen for this study, because you have a tendinopathy

**Do I have to take part?**

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive. Should you withdraw from the study after initially taking part; the results from the injections already done on you will still be used in the final analysis of the results of the study, as with all results in the study this will be anonymised.

**What will happen to me if I take part?**

If you agree to take part in this study, you will have the normal outpatient assessment that **all** patients have. The trial is a double blind randomized trial. This means that although all patients will have blood taken from them only those selected by chance by the computer will have it injected into their tendinopathy, those that do not will have normal saline injected. Neither will you as the patient nor the clinician doing the injection know what is being injected, hence double blind. However a second clinician also present will be fully aware.

All injections will be performed by your clinicians under ultrasound guidance – using the ultrasound machine to make sure it is in the correct place.

In studies like this where we are comparing 2 treatment options, it is important that the patient, the doctors, and physiotherapists that see you after the procedure do **not** know what treatment you have had, (although, if your doctor needs to find out he/she can do so). This is because **knowing** what treatment you have had could influence the overall outcome. Therefore you will **not know** what treatment you have had until the end of the study.

Each patient will normally go home, on the same day of the injection.

Each patient will be seen at six weeks, three, six and twelve months after the injection, to assess their progress.

Note, you will **not** have to attend more clinics than normal for this study, and the consultations should not take significantly longer than normal.

**What do I have to do?**

Your rehabilitation following your injection will not be altered by your participation in the study. You will be encouraged to move and use the affected part according to a guidance sheet that you will be given.

**What are the alternative forms of treatment?**

Continue a programme of eccentric exercises though you have been chosen as this has failed. Consider further anti-inflammatory medication or injection, again you have been chosen as this has not worked and there is a risk of tendon rupture associated with this. There is also the option of surgery.

**What are the possible disadvantages and risks of taking part?**

As with any injection there is risk of local tenderness and bruising at injection site which should be temporary. The pain at the site of the injection should be limited to that area and can last up to 1 week although in most cases no longer than 48 hours. The pain should be the same regardless of whether autologous blood or normal saline is injected. There is a temporary risk of flaring up symptoms in which case simple analgesia – paracetamol is advised. There is the risk that the injection may not work. There is a 1 in 10,000 risk of infection however we take all necessary precautions against this.

**What are the possible benefits of taking part?**

Patients in both groups of the study could gain a significant improvement in their symptoms. However, as with other treatments this cannot be 100% guaranteed. The information we get from this will help us and other clinicians determine the best treatment for tendinopathy.

**What if new information becomes available?**

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your research clinician will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw your research clinician will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form.

Also, on receiving new information your research clinician might consider it to be in your best interests to withdraw you from the study. They will explain the reasons and arrange for your care to continue.

**What if something goes wrong?**

Hopefully, there should be no problems during the study. If you are harmed by taking part in this research project there are no special compensation arrangements. However, if you are unhappy with any aspect of your treatment, the normal National Health Service complaints mechanisms will be available to you. If you are harmed due to someone’s negligence then you may have grounds for legal action, but you may have to pay for it.

***Will my taking part in this study be kept confidential?***

All information which is collected about you during the course of this research will be kept strictly confidential. Any information about you which leaves the hospital will have your name and address **removed** so that you cannot be recognised from it.

Your GP will be notified of your participation in the trial.

**What will happen to the results of the research study?**

The results of the trial will be collated, and should be published. A copy of the published paper can be obtained from us, if requested. The treatment that each patient received will be made available to each patient at the end of the trial. Each patient will not be identified in any publication.

**Who is organising and funding the research?**

The study is being organized by the Sports and Exercise Medicine Department, Homerton University Hospital.

***Who has reviewed the study?***

The study has been reviewed by the Research Ethics Committee.

**Contact for further information**

**Dr S Mughal**

**Mr P Resteghini**

**Mr Z Sivardeen**

Homerton University Hospital

London E9 6SR

Tel: 020 8510 5751

Fax:020 8510 7796

Each patient will be given a copy of this Information Sheet and a signed Consent Form to keep.

***Thank you***

If you are taking part in the study we would all like to thank you for reading this information and taking part. If you are not taking part we would like to thank you for reading the information.

***3. NICE Patient Information Sheet***

A PDF file is available on request

***4. Letter to GP***

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Dear Dr

This is to inform you that your patient...........................................................................................

Has kindly agreed to participate in a study we are performing at Homerton University Hospital.

The study aims to investigate the use of autologous blood injections for chronic tendinopathy.

The participation in the study will involve each patient having blood taken from them and either injected with their autologous blood or with normal saline and will subsequently be followed up in out-patients by ourselves.

If you have any queries, please contact Dr Shabaaz Mughal or Mr. Peter Resteghini or Mr. Zialli Sivardeen at Homerton University Hospital.

Yours sincerely

Dr S Mughal StR Sports and Exercise Medicine.

Mr P Resteghini Consultant Physiotherapist Musculoskeletal Rehabilitation

Mr Z Sivardeen Consultant Orthopaedic Surgeon