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PARTICIPANT INFORMATION SHEET (PIS)

Study title: A feasibility multicentre randomised controlled trial comparing Wide-awake Local Anaesthesia No Tourniquet (WALANT) versus General and Regional Anaesthesia for Flexor Tendon Repair (WAFER Trial)

Chief Investigator: Professor Afshin Mosahebi

We'd like to invite you to take part in our research study. Joining the study is entirely up to you, before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through this information sheet with you, to help you decide whether or not you would like to take part and answer any questions you may have. We'd suggest this should take about 10 minutes. Please feel free to talk to others about the study if you wish.

The first part of the Participant Information Sheet tells you the purpose of the study and what will happen to you if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Please ask us if there is anything that is not clear. Take time to decide whether or not you wish to take part.

Part 1

What is the purpose of the study?

In the hand, flexor tendons help with bending the fingers and thumb and help with making a fist. Injury to finger tendons is very common following a cut to the hand and can cause loss of finger function. Hence, a cut finger tendon requires surgical repair to stitch the divided tendon ends to regain normal function.

This procedure is usually performed when a patient is fully unconscious (general anaesthesia) or by blocking the nerve supply to the entire arm to make it numb (regional anaesthesia). During this procedure, a tourniquet is used to control bleeding to provide the surgeon a clear vision of the cut ends of the tendon. A recent advancement enables this procedure to be performed by only giving an injection to numb the hand (local anaesthesia) which is mixed with adrenaline to control bleeding (a procedure called WALANT). This enables the surgery to be performed while patient is fully awake without using a tourniquet. In addition to decreasing the pain related to tourniquet use, importantly, the surgeon can check the quality of the repair by asking the patient to move the finger and make any adjustments to the repair during the surgery.

We wish to evaluate WALANT as an alternative to regional or general anaesthesia for the surgical management of flexor tendon injuries. We plan to include 60 participants in this trial, in which half will receive the new approach and the remaining will receive the standard of care (regional or general anaesthetic). The choice of treatment will be decided by chance to ensure that similar type of patients receive both approaches. The reason we are doing this study is to see whether this kind of trial is acceptable to patients and clinicians and to help design a larger trial that will really help us see if the new approach or standard of care is better for the patients and NHS.

Why have I been invited?
You have been invited to participate in this study because you have recently had a traumatic flexor tendon injury and your plastic surgeon considers that you may benefit from having surgery under WALANT.

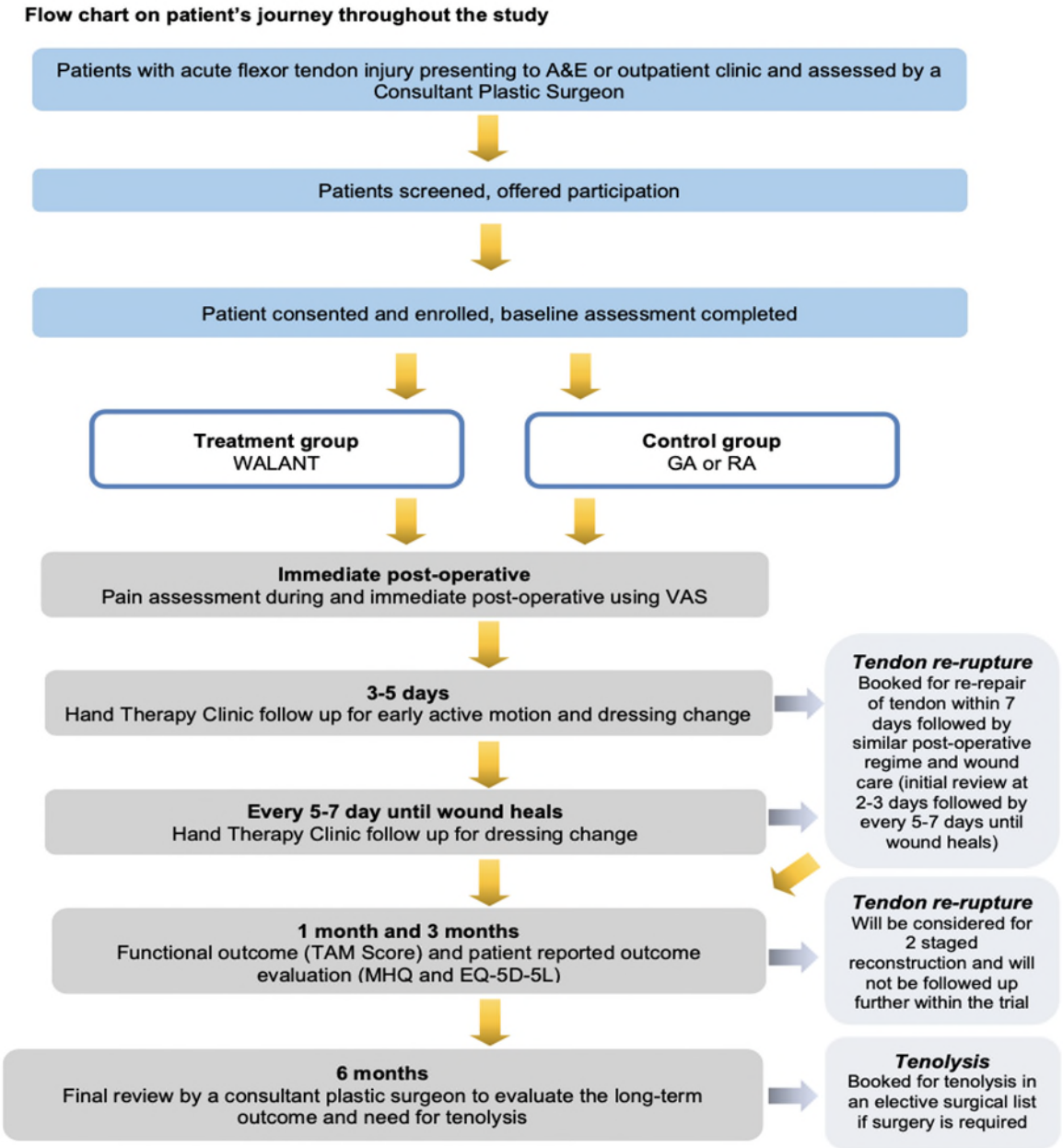
Do I have to take part?
It is up to you to decide whether or not to take part. We will explain the study and go through this information sheet. If you do decide to take part, you will be given this information sheet to keep and will be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time or not take part will not affect the standard of care you receive.

What would taking part involve?

You will be provided with this Patient Information Leaflet and given appropriate time to consider the trial and ask any questions. Following signing a consent form, you will be enrolled into the study. Sometimes we don't know which way of treating patients is best. To find out, we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same to start with, each patient is put into a group by chance (randomly). You will be randomly allocated to either of the treatments (WALANT or GA/RA) on a 1:1 basis based on a computer-generated sequence. You will then be informed and explained further regarding the treatment that is assigned to you by a member of the research team. Following this, you will undergo surgery for the repair of your flexor tendon(s) in the operating theater as per current standard of care. During the surgery and immediately after the operation, we will assess your pain (if any). Almost all patients will be discharged the same day. Following discharge, you will have a hand therapy clinic appointment within 3-5 days to commence physiotherapy and have your dressings changed. With your consent, we will inform your GP about your participation in this study. As part of our standard procedure, all patients will then have follow up appointments with the hand therapy team for further physio and dressing changes every 5-7 days until the wound heals. If you experience a tendon re-rupture within 1 month of the operation, you will be booked for a re-repair of tendon within 7 days following a similar postoperative protocol. At 1 and 3 months after the operation you will be followed up and assessed to check the functional outcome of your hand and asked some questions regarding your wellbeing and how you are finding the function of your hand. Also, at 3 months following the operation we will assess the functional outcome of your hand by examining it in clinic. If you experience a tendon re-rupture following 1 month after the operation, you will be considered for a 2-staged elective operation to reconstruct your tendon and you will no longer be followed up in the trial. Your final review will be at 6 months following the operation, where you will see a consultant plastic surgeon to evaluate the long-term outcome, check for any complications and see whether you need any further operations to help with the mobility of your finger.

Your journey throughout the study is summarised in the flow chart below (Figure 1).

Figure 1: Flow chart on patient's journey throughout the study



What data will be collected?

Some parts of your medical record will be included into this study. As mentioned above, several assessments will be done over the 6 months that you are in the trial. We will record using specific questionnaires: your assessment of pain during and after the operation, the functional outcome of your hand, your experience of the function of your hand and your wellbeing.
All information which is collected about you during the course of the research will be kept strictly confidential. Your will be given a unique trial identification number which will be used for identification in the trial documents. Any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised from it. The data from this study may be used to design the next phase of this study but your information will be kept strictly confidential.

What are the possible benefits of taking part?

It is possible that there may be no direct benefits from taking part in this study, however the information obtained from this study may likely benefit future patients.

What are the possible disadvantages and risks of taking part?

There are no direct disadvantages or risks of taking part in this study as all procedures are performed in our centre as current clinical practice. The risk involved is related to the surgical procedure of flexor tendon repair, which is a routine surgical procedure performed in our centre.
The procedure will be done by experienced plastic surgeons. The procedures are commonly performed with excellent safety profile.
The choice of anaesthetic should not affect the healing of your wound, and should you become concerned about your wound at any time, a further outpatient follow-up appointment can be arranged.

The standard risks for all flexor tendon repair operations can be best categorised into immediate, early and late risks. The immediate risks during the procedure are a less than 1 in 20 risk of needing to extend the surgical incision to locate the tendon and a less than 1 in 100 risk of damage to the surrounding structures such as the nerves to your fingers which can lead to a change in sensation, or vessels which can result in bleeding. Early risks in the days after your surgery include discomfort, hand stiffness, swelling and bruising, and complications such as infections which may result in further procedures. Later risks in the weeks or months after the procedure include development of a visible scar, less than 1 in 20 risk of tendon re-rupture or tendon adhesions, and a less than 1 in 100 risk of complex regional pain syndrome. Complex regional pain syndrome us a rare type of chronic pain which is often triggered by an injury or surgical procedure.

What do I have to do?

After having the operation, the only key essential study requirements are that you attend all scheduled follow up visits in order to allow us to assess you over 6 months.

What if relevant new information becomes available?

Sometimes during the course of a research project, new information becomes available about the subject being studied. If this happens your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw your research doctor 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. It is possible that on receiving new information your research doctor might consider it to be in your best interests to withdraw from the study. He/she will explain the reasons and arrange for care to continue. Should new information become available during the duration of the study that can impact your treatment or care, you will be updated you as soon as possible. If you have any further concern, please do not hesitate to discuss with the treating consultant surgeon

What happens when the research study stops?

At the end of the study, or if you withdraw from the trial, your study doctor will assess your symptoms, discuss your options and plan the appropriate treatment. On occasion, studies stop study before it has finished. If this happens, your study doctor will explain the reasons why and arrange appropriate care for you.

What will happen if I don't want to carry on with the study?

Your participation in this study is voluntary. If you agree to take part and then change your mind, it is your right to withdraw at any time without this decision affecting your future care. If you decide not to take part, your doctor will discuss your future care with you. Your legal rights will not be affected by agreeing to take part in or withdrawing from the study. At the end of the study your Doctor will discuss future treatment options. You are free to withdraw from the study at any time without giving a reason. If you decide to withdraw from the study, this will not affect the standard of your routine care in any way. Your doctor will continue to treat you with the same level of care.

With your permission, we would like to keep the information collected already but would not collect any more.

What if there is a problem?
Any complaint about the way you have been dealt with or any possible harm you might suffer will be addressed. The detailed information on this is given in part 2.

This completes Part 1. If the information in Part 1 has interested you and you are considering participation, please read the additional information in part 2 before making any decision.

Part 2

What if there is a problem?

If you experience any problem from the treatment, you should contact us straight away. We will take every care in the course of this study however in the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for but you may have to pay your legal costs. If you wish to complain about your treatment by members of staff due to your participation in the research, National Health Service complaints mechanisms are available to you. Please ask your researcher if you would like more information on this.

In the unlikely event that you are harmed by taking part in this study, or if you have concern about any about any aspect of this study, you should ask to speak to a member of the study team who will do their best to answer your questions

Complaints
If you wish to complain or have any concerns about any aspect of the way you have been treated during the course of this study then you speak with the researchers who will do their best to answer your questions or concerns.

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Mr Dariush Nikkhah, Consultant Plastic Surgeon,
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The normal National Health Service complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Research and Development Office at the Royal Free at rf.randd@nhs.net or the Patient advice & liaison service (PALS)
Royal Free Hospital PALS: 020 7472 6446 or 020 7472 6447
Fax: 020 7472 6463
Text: 07624 803635 (deaf users only)
E-mail: rf.pals@nhs.net
The PALS office is on the ground floor in the hospital's main reception. The PALS office is open Monday to Friday 10am-4pm.

Harm
In the event that something goes wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for legal action for compensation against the sponsor (Royal Free London NHS Foundation Trust), but you may have to pay your legal costs. The normal NHS complaints mechanism will still be available to you.

How will we use information about you?
We will need to use information from you and from your medical records for this research project.

This information will include your initials/ NHS number/ name/ contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly.
People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.
We will keep all information about you safe and secure.
Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are my choices about how my information is used?
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 need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records. If you do not want this to happen, tell us and we will stop.
If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Will my taking part in this study be kept confidential?
All information which is collected about you during the course of the research will be kept strictly confidential. Your will be given a unique trial identification number which will be used for identification in the trial documents. Any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised from it. The data from this study may be used to design the next phase of this study but your information will be kept strictly confidential.

How will my data be used and protected (General Data Protection Regulation)?
Royal Free London NHS Foundation Trust R&D is the sponsor for this study based in the United Kingdom. We will be using information from you and/or your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Royal Free London will keep identifiable information about you for 6-12 months after the study has finished.
Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible.
You can find out more about how we use your information by contacting the phone numbers provided at the end of this leaflet.

How will these data be collected (General Data Protection Regulation)?
Royal Free London NHS Foundation Trust will collect information from you and/or your medical records for this research study in accordance with our instructions.
Royal Free London NHS Foundation Trust is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Royal Free Hospital London will be the main recruiting site. Royal Free London NHS Foundation Trust will keep identifiable information about you for the purpose of the study for 6-12 months after the study has finished. This information will be held by the sponsor organisation.
Royal Free London NHS Foundation Trust will keep your name, NHS number, date of birth and contact details confidential. Royal Free London NHS Foundation Trust will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from Royal Free London NHS Foundation Trust R&D and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Royal Free London NHS Foundation Trust R&D will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number, date of birth or contact details.
Royal Free London NHS Foundation Trust will keep identifiable information about you from this study for 6-12 months after the study has finished. Research data generated (without identifiable information) and collected samples will be stored for five years following completion of the study.

Will my data be collected indirectly form medical records or database (General Data Protection Regulation)?

Royal Free London NHS Foundation Trust will collect information about you for this research study from previously collected medical records or database. The previously collected medical records or database will not provide any identifying information about you to Royal Free London NHS Foundation Trust R&D. We will use this information to confirm eligibility and to complete our study record.

Will the collected data is intended to or likely to be used for future research (General Data Protection Regulation)?
When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.
This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

Where can you find out more about how your information is used?
You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to the Data Protection Officer: smondal@nhs.net
- visiting the Trust webpage at www.royalfree.nhs.uk/patients-visitors/privacy-statement/

What will happen to the results of the research study?
We plan to run the study for 2 years, after which the research team will analyse the results. The results will be published as soon as possible after study completion. You will not be identified in any report or publication. A lay summary of the results will be sent to all study participants.

Who is organising and funding the research?
This research is organised by the Department of Plastic Surgery at the Royal Free Hospital London. This research is sponsored by the Royal Free London NHS Foundation Trust and funded by National Institute for Health and Care Research (NIHR, UK).

Commercial Involvement
There is no commercial involvement in this study.

How have patients and the public been involved in this study?
Patient representatives who have had flexor tendon injury are part of our study team and were involved in the design of this trial and contributed to the discussion on the research question and outcomes via online surveys and a focus group meeting. A total of 27 patients were involved in the online survey and another 12 patients were involved in a focus group meeting to identify priorities and outcomes of a flexor tendon study. Over 95% of participants of the survey agreed that this study should be performed and 83% of the patients said that they were willing to participate in such a study. The focus group participants suggested that important outcomes that should be compared are functional outcome, patient satisfaction and the difference in complications.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee (REC), to protect your interests. This study has been reviewed and given favorable opinion by the Research Ethics Committee. This study was also reviewed by the National Institute for Health and Care Research (NIHR, UK).

Contact details for further information

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Thank you for taking the time to read this information sheet. If you would like to take part, you will be asked to sign a consent form; one for you to keep, one for the investigator and one for your medical records.