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A study to evaluate operation of flexor tendon injury under local anaesthesia compared to general or regional anaesthesia

Submission date
05/12/2022

Recruitment status
No longer recruiting

Registration date
12/12/2022

Overall study status
Completed

Last Edited
17/06/2025

Condition category
Surgery

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
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)(SoC). 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 ('new approach'). 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. Several preliminary studies have reported that the new approach may provide functional benefit and cost effectiveness, but there is uncertainty about these findings. As a result, there is variation in clinical practice.
We aim to perform a feasibility study to establish whether it is possible to conduct a study to compare operations of flexor tendon injuries while patients are awake and without tourniquet (a tight band applied over the arm to control bleeding) ('new approach') compared to current 'standard of care'(SoC).

Who can participate?
Adults over 18 years, with flexor tendon injury.

What does the study involve?
We will include 60 participants with flexor tendon injury: half will receive the new approach and the remaining will receive SoC. The choice of treatment will be decided by chance to ensure that similar type of patients receive the new approach and the SoC. This study will look at whether this type of study is acceptable to patients and clinicians and will help design a larger trial to find out if the new approach or SoC is better for patients and NHS.

What are the possible benefits and risks of participating?
Benefits:
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.
Risks:
There are no direct disadvantages or risks of taking part in this study as all procedures are performed in our centre as per 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 an 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 the 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 is a rare type of chronic pain which is often triggered by an injury or surgical procedure.

Where is the study run from?
Royal Free Hospital (UK)

When is the study starting and how long is it expected to run for?
December 2022 to April 2025

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Muholan Kanapathy, m.kanapathy@ucl.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 54149, NIHR203610, IRAS 315954

Study information

Scientific Title
A feasibility multicentre randomised controlled trial comparing Wide-awake Local Anaesthesia No Tourniquet (WALANT) versus General and Regional Anaesthesia (GA/RA) for Flexor Tendon Repair (WAFER Trial)

Acronym
WAFER

Study objectives
Aim: To perform a feasibility study to establish whether it is possible to conduct a study to compare operations of flexor tendon injuries while patients are awake and without tourniquet (WALANT) compared to current ‘standard of care’.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/11/2022, London - City & East Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 207 104 8144; cityandeast.rec@hra.nhs.uk), ref: 22/PR/1197

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Surgery for flexor tendon injuries

Interventions
Current intervention as of 09/06/2023:
Multicentre, single-blinded, feasibility RCT with 2 parallel groups (WALANT Vs. GA/RA). Randomisation will be performed by minimisation technique with an element of randomisation. Blinding of participants and healthcare providers will be impossible. The outcome assessors assessing the outcomes will be blinded to the groups. The study participants will be recruited over 16 months and participants in both groups are to be followed up for 6 months.
A total of 60 patients will be recruited in the study, with 30 patients in each arm.

Research participant design and methodology:
1. The population of participants will be those present with acute flexor tendon injury following assessment and review by a Consultant Plastic Surgeon. Participants will be identified from A&E or outpatient clinic.
2. Participants will be offered participation in the study, provided with a Patient Information Sheet (PIS) and will be allowed time prior to obtaining informed consent.
3. Participants will be consented. Baseline assessment will be performed using a Patient Assessment Form. All patients will have a quality-of-life assessment (EQ-5D-5L) and productivity assessment (WPAI-SHP) at baseline.
4. Participants will be randomised to either the treatment group (WALANT) or the control group (GA or RA).
5. Patients in the treatment group will undergo flexor tendon repair under WALANT

6. Patients in the control group will undergo flexor tendon repair under GA or RA.
7. All patients will undergo a pain assessment immediately post-operatively using the Visual Analog Score (VAS)
8. All patients will have a hand therapy clinic appointment within 3-5 days to commence early active motion and have dressings changed.
9. All patients will have follow-up appointments with the hand therapy team for further physio and dressing changes every 5-7 days for 1 month and then as clinically required as per BSSH guidelines.
10. If any patients experience a tendon re-rupture within 1 month of their operation, they will be booked for a re-repair of tendon within 7 days followed by similar post-operative regime and wound care (initial review at 2-3 days followed by every 5-7 days for a month).
11. At 1, 3 and 6 months post-operatively: All participants will have functional outcome of the hand assessed using Total Active Motion (TAM) score; patient reported evaluation using Michigan Hand Outcomes Questionnaire (MHQ); health related quality of life assessment using EQ-5D-5L questionnaire; work productivity loss assessment using WPAI-SHP questionnaire.
12. If any patients experience a tendon re-rupture following 1 month post-operatively, they will be considered for a 2-staged reconstruction and they will not be followed up further with the trial.
13. At 6 months all patients will have a final review with a consultant plastic surgeon to evaluate the long-term outcome, overall complication and need for tenolysis.
14. Any patients that require a tenolysis will be booked for a tenolysis on an elective surgery list.

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Multicentre, single-blinded, feasibility RCT with 2 parallel groups (WALANT Vs. GA/RA). Randomisation will be performed by minimisation technique with an element of randomisation. Blinding of participants and healthcare providers will be impossible. The outcome assessors assessing the outcomes will be blinded to the groups. The study participants will be recruited over 16 months and participants in both groups are to be followed up for 6 months.
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4. Participants will be randomised to either the treatment group (WALANT) or the control group (GA or RA).
5. Patients in the treatment group will undergo flexor tendon repair under WALANT
6. Patients in the control group will undergo flexor tendon repair under GA or RA.
7. All patients will undergo a pain assessment during and immediately post operatively using the Visual Analog Score (VAS)
8. All patients will have a hand therapy clinic appointment within 3-5 days to commence early active motion and have dressings changed.
9. All patients will have follow up appointments with the hand therapy team for further physio and dressing changes every 5-7 days until the wound heals.
10. If any patients experience a tendon re-rupture within 1 month of their operation, they will be booked for a re-repair of tendon within 7 days followed by similar post-operative regime and

wound care (initial review at 2-3 days followed by every 5-7 days until the wound heals).
11. At 1 and 3 months post-operatively: All participants will have patient reported evaluation using Michigan Hand Outcomes Questionnaire (MHQ); and health related quality of life assessment using EQ-5D-5L questionnaire.
12. At 3 months post operatively: all patients will have functional outcomes assessed using Total Active Motion (TAM) score;
13. If any patients experience a tendon re-rupture following 1 month post-operatively, they will be considered for a 2-staged reconstruction and they will not be followed up further with the trial.
14. All patients will have a final review with a consultant plastic surgeon to evaluate the long-term outcome, overall complication and need for tenolysis.
15. Any patients that require a tenolysis will be booked for a tenolysis on an elective surgery list.

Intervention Type
Procedure/Surgery

Primary outcome measure
Current primary outcome measures as of 09/06/2023:
1. Recruitment rate of the trial measured over 16 months (duration of recruitment)
2. Support for the trial from involved clinicians assessed through qualitative interviews over the duration of the trial
3. Equipoise amongst clinicians and patients assessed through qualitative interviews over the duration of the trial
4. Rate of participant withdrawal/drop-out from the study assessed throughout the duration of the trial

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Previous primary outcome measure:
Recuitment rate measured using patient records at end of study

Secondary outcome measures
Current secondary outcome measures as of 09/06/2023:
1. Proportion with good functional outcome measured using Total Active Motion (TAM) score with a goniometer at 1, 3 and 6 months
2.Grip strength measured using a dynamometer at 1, 3, and 6 months.
3. Pinch strength measured using a pinch gauge at 1, 3, and 6 months
4. Post-operative finger oedema assessed by measuring finger circumference at 1, 3, and 6 months
5. Patient-reported outcome assessed using the Michigan Hand Outcomes Questionnaire (MHQ) at 1, 3 and 6 months
6. Productivity impact assessed using the Work Productivity and Activity Impairment Questionnaire: Specific Health Problem (WPAI-SHP) at baseline, 1, 3 and 6 months
7. Health-related quality of life assessed using the EQ-5D-5L questionnaire at baseline, 1, 3 and 6 months
8. Post-operative pain assessed using visual analogue score (VAS) tool immediately post-operatively
9. Incidence of tendon ruptures following repair assessed clinically at 1, 3 and 6 months
10. Incidence of tenolysis assessed clinically at 6 months
11. Incidence of overall complications at 6 months
12. Incidence of adverse events assessed throughout the duration of the trial

13. Healthcare resource use assessed through micro-costing analysis throughout the duration of the trial

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Previous secondary outcome measures:
1. Patient reported Health-related quality of life questionnaire (EQ-5D-5L) at 1 and 3 months after surgery
2. Functional assessment of hand - recorded using Total active motion score at 3 - 5 days after surgery
3. Change of dressing measured using patient records at end of study
4. Hand therapy measured using patient records at end of study

Overall study start date
01/12/2022

Completion date
01/04/2025

Eligibility

Key inclusion criteria
1. Adults >=18 years old
2. Clinical diagnosis of acute flexor tendon injury (100% transected) involving Flexor digitorum profundus and/or Flexor digitorum superficialis, and/or Flexor pollicis longus of the hand
3. Single digit or two digits injury
4. Patient understands and is willing to participate and can comply with follow up regime

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Total final enrolment
60

Key exclusion criteria
1. Tendon not amendable to primary repair (gross wound contamination, segmental tendon loss, associated fractures or mangled hand injuries)
2. Secondary tendon repair or reconstruction

3. History of allergy to Local anaesthetic (LA)
4. Refusal to have LA or deemed non-cooperative to be performed without sedation
5. Pre-existing deformity of finger or hand
6. High risk for GA or not fit for surgery (American society of anaesthesiologist grade >4)

Date of first enrolment
01/03/2023

Date of final enrolment
31/07/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Free Hospital
Pond Street
London
United Kingdom
NW3 2QG

Study participating centre
Manchester University NHS Foundation Trust
Wythenshaw Hospital
Southmoor Rd
Wythenshawe
Manchester
United Kingdom
M23 9LT

Study participating centre
United Leeds Teaching Hospitals NHS Trust
Trust Offices
Leeds General Infirmary
Great George Street
Leeds
United Kingdom
LS1 3EX

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
London
United Kingdom
E1 2ES

Sponsor information

Organisation
Royal Free London NHS Foundation Trust

Sponsor details
Royal Free Hospital
Pond Street
London
England
United Kingdom
NW3 2QG
+44 20 7794 0500
rf-tr.sponsoredresearch@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.royalfree.nhs.uk/

ROR
https://ror.org/04rtdp853

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Results and Publications

Publication and dissemination plan
The results will be presented in medical conferences and published in medical journals, patient information websites, and social media platforms.

Intention to publish date
31/05/2026

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.1	16/11/2022	07/12/2022	No	Yes
HRA research summary			28/06/2023	No	No
Protocol article		28/08/2023	29/08/2023	Yes	No