Microsurgical nerve repair in adult patients with recent traumatic digital nerve injury

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
26/02/2020		[X] Protocol		
Registration date 28/02/2020	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 05/09/2025	Condition category Injury, Occupational Diseases, Poisoning	Individual participant data		

Plain English summary of protocol

Background and study aims

Digital nerves are small nerves that pass along the side of each finger and provide sensation to the fingertips. These nerves can be accidentally cut when handling sharp objects like a knife or broken glass. The NEON study aims to find out whether sewing the ends of the cut nerve surgically is beneficial or even needed. Thoroughly cleaning the cut wound before closing the skin is a much simpler procedure, and may be satisfactory for patients.

There is some evidence that both treatments give good results. There is also some evidence that patients may not fully recover the feeling in their injured finger, even after sewing the nerve. Research so far has been conflicting and is of varying quality. For example, some studies do not directly compare treatments, or do not ask patients about their views of recovery. The best way to find out if stitching the cut digital nerve is appropriate is to conduct a research study. NEON will compare surgical procedures for digital nerve injury, with or without stitches (also known as sutures). 478 patients will have one of these two treatment options by random allocation.

Who can participate?

Patients aged 18 years and above with a suspected complete digital nerve laceration in any single digit, including thumb and little finger, appropriate for surgical repair.

What does the study involve?

Patient questionnaires measuring fingertip sensation and quality of life will assess the benefit of each treatment up to 12 months after the operation. It will also be important to look into whether there is a difference in cost between the two treatments.

What are the possible benefits and risks of participating?

The researchers cannot guarantee a benefit to patients who take part in this study. The results from the study are likely to benefit future patients with nerve injuries.

Both procedures are already performed routinely in the NHS and there is no expected difference in risk between them, or to treatment outside of the study. Taking part in the study will not change the standard of care patients receive. If patients are concerned about the complications associated with this injury and surgery, the researchers advise they speak to their local care team

Where is the study run from?
University of Oxford Surgical Intervention Trials Unit (SITU) (UK)

When is the study starting and how long is it expected to run for? April 2020 to December 2023

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

Who is the main contact? SITU-NDORMS team situ@ndorms.ox.ac.uk Associate Prof. Jain (scientific) situ@ndorms.ox.ac.uk

Contact information

Type(s)

Public

Contact name

Dr SITU-NDORMS Team

Contact details

Surgical Intervention Trials Unit (SITU)
Nuffield Department of Orthopaedics Rheumatology and Musculoskeletal Sciences
University of Oxford
Botnar Research Centre
Windmill Road
Oxford
United Kingdom
OX3 7LD
+44 (0)1865 737929
situ@ndorms.ox.ac.uk

Type(s)

Scientific

Contact name

Prof Abhilash Jain

ORCID ID

https://orcid.org/0000-0002-1799-5310

Contact details

Surgical Intervention Trials Unit (SITU)
Nuffield Department of Orthopaedics Rheumatology and Musculoskeletal Sciences
University of Oxford
Botnar Research Centre
Windmill Road

Oxford United Kingdom OX3 7LD +44 (0)1865 737929 situ@ndorms.ox.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

258872

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

IRAS 258872

Study information

Scientific Title

A randomised controlled trial assessing if microsurgical nerve repair offers clinical benefit and cost effectiveness (in terms of patient–reported hand function, sensory recovery and adverse events) over exploration and washout without microsurgical nerve repair in adult patients with recent traumatic digital nerve injury

Acronym

NEON

Study objectives

The NEON study seeks to answer whether microsurgical digital nerve repair is clinically and cost effective.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 10/02/2020 South Central - Oxford B Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)2071048046; nrescommittee. southcentral-oxfordb@nhs.net), ref: 20/SC/0018

Study design

Multi-centre parallel double-blinded (patient and assessor) two-arm randomized controlled trial including economic analysis

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Single unilateral digital nerve injury appropriate for surgical repair

Interventions

Patients are randomised in theatre after consent and after confirmation of eligibility through surgical exploration. A web-based randomisation system will be used and the allocations will be computer-generated with a 1:1 ratio, minimised by site, injury location and flexor tendon injury. The patient will receive one of the following treatments in theatre:

- 1 Digital nerve surgery with microsurgical sutures
- 2 Digital nerve surgery with realignment of nerve ends but no microsurgical sutures Patients will be followed up for 12 months by completing questionnaires and by attending clinical assessments. Patients will be followed up for a further 12 months using medical records and routine data.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Clinical effectiveness of microsurgical nerve repair measured by the Impact of Hand Nerve Disorders (I-HaND) Patient Reported Outcome Measure at 12 months post-randomisation

Key secondary outcome(s))

- 1. Neurosensory and functional recovery measured at 3 and 12 months post-randomisation by:
- 1.1. Hand Health Profile of the Patient Evaluation Measure
- 1.2. EQ-5D-5L index and -EQ-VAS
- 1.3. Static two-point discrimination test (2PD)
- 1.4. Tactile gnosis using Shape/Texture Identification (STI) test; and Touch thresholds using Weinstein Enhanced Sensory Test (WEST) monofilaments
- 2. Cost-effectiveness of microsurgical nerve repair, measured by Health resource use questionnaires and EQ-5D-5L index at 3 and 12 months post randomisation
- 3. Complications of surgery and clinically problematic neuroma rates measured at 3 and 12 months post-randomisation by:
- 3.1. Patient-reported complications
- 3.2. Clinical assessment (including Elliot score)
- 3.3. Complications and further procedures in medical records
- 3.4. Complications and further procedures based on medical records and routine data at 24 months post randomisation

Completion date

01/12/2023

Eligibility

Key inclusion criteria

Patients aged 18 years and above with a suspected complete digital nerve laceration in any single digit, including thumb and little finger, appropriate for surgical repair

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

122

Key exclusion criteria

- 1. Bilateral injury (ie both radial and ulnar digital nerves)
- 2. Laceration outside the region between distal palmar crease and distal interphalangeal joint
- 3. Closed injury
- 4. Infected wounds
- 5. Injuries in which a significant nerve gap exists which would preclude direct tension free surgical end-end repair
- 6. Non-isolated or multi-level injury (ie common digital/wrist nerve injury, fracture)
- 7. Unable to give consent
- 8. Inability to comply with trial follow-up procedures
- 9. Date of surgery later than 10 days after injury

Date of first enrolment

15/09/2020

Date of final enrolment

11/11/2022

Locations

Countries of recruitment

United Kingdom

England

Study participating centre Stoke Mandeville Hospital Buckinghamshire Healthcare NHS Trust

Mandeville Road

Aylesbury United Kingdom HP21 8AL

Study participating centre Broomfield Hospital

Mid and South Essex NHS Foundation Trust Court Road Chelmsford United Kingdom CM1 7ET

Study participating centre University Hospital Coventry

University Hospitals Coventry and Warwickshire NHS Trust Clifford Bridge Road Coventry United Kingdom CV2 2DX

Study participating centre

Royal Cornwall Hospital

Royal Cornwall Hospitals NHS Trust Treliske United Kingdom TR1 3HD

Study participating centre Royal Derby Hospital

University Hospitals of Derby and Burton NHS Foundation Trust Uttoxeter Road Derby United Kingdom DE22 3NE

Study participating centre Queen Victoria Hospital

Queen Victoria Hospital NHS Foundation Trust Holtye Road East Grinstead United Kingdom RH19 3DZ

Study participating centre Basingstoke and North Hampshire Hospital

Hampshire Hospitals NHS Foundation Trust Aldermaston Road Basingstoke United Kingdom RG24 9NA

Study participating centre John Radcliffe Hospital

Oxford University Hospitals NHS Foundation Trust Headley Way Headington Oxford United Kingdom OX3 9DU

Sponsor information

Organisation

University of Oxford

ROR

https://ror.org/052gg0110

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. situ@ndorms.ox.ac.uk

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		02/09/2025	05/09/2025	Yes	No
HRA research summary			28/06/2023		No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 3.0	02/07/2020	03/05/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes