ISRCTN16211574 https://doi.org/10.1186/ISRCTN16211574

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

Submission date
26/02/2020

Recruitment status
No longer recruiting

Registration date
28/02/2020

Overall study status
Completed

Last Edited
27/11/2024

Condition category
Injury, Occupational Diseases, Poisoning

[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
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

Study website
https://neon.octru.ox.ac.uk/welcome-neon-trial

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
http://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

EudraCT/CTIS number
Nil known

IRAS number
258872

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not yet available in web format, please use the contact details to request a patient information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
01/10/2019

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
478

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
England

United Kingdom

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

Sponsor details
Clinical Trials and Research Governance
Address Joint Research Office
Boundary Brook House

Churchill Drive
Oxford
England
United Kingdom
OX3 7GB
+44 (0)1865 616480
ctrg@admin.ox.ac.uk

Sponsor type
University/education

Website
http://www.ox.ac.uk/

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

Publication and dissemination plan
Protocol will be published before the end of the study recruitment period, other documents will be available on request. Planned publication of the study results in a high-impact peer reviewed journal.

Intention to publish date
31/03/2024

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?
Protocol file	version 3.0	02/07/2020	03/05/2023	No	No
HRA research summary			28/06/2023	No	No