

CoNNECT: A study of sutureless nerve repair

Submission date 24/07/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/02/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 11/11/2024	Condition category Surgery	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

There are approximately 300,000 cases of traumatic nerve injuries in the hand per year in Europe. Current methods of nerve repair have limited benefits - approximately 33% of patients with a traumatic nerve injury do not regain useful sensitivity of the finger. A nerve injury is repaired by joining the two cut ends of the nerve with stitches using a microscope. Recently, there has been published data suggesting that a nerve conduit (a flexible tube used to bridge between the two ends of a cut nerve) may protect a repaired nerve and reduce scar formation at the site of repair. The aim of this study is to find out which of the three methods of nerve repair provides the best results and provide a lower rate of complications from the surgery. The current gold standard is stitching injured nerve ends directly together. The other methods are stitching nerve ends directly together and placing a nerve conduit around it, or placing the injured nerve ends together without stitches and using the nerve conduit to maintain their position and heal

Who can participate?

Patients aged 16-75 with a traumatic complete digital nerve injury between the wrist and middle of the affected finger that is less than 10 days old

What does the study involve?

Patients will be randomly allocated a treatment method, decided by a computer programme. Only the surgical team will know which method is being used. The patient and hand therapists involved will not be told. The treatment methods are the following:

1. Stitching injured nerve ends directly together.
2. Stitching nerve ends directly together and placing a nerve conduit around it
3. Placing the injured nerve ends together without stitches and using the nerve conduit to maintain their position and heal

Patients will be asked to fill in a short pre-operative questionnaire. Following the operation, patients will need to attend follow up appointments at 2 weeks, 6 weeks, 12 weeks, 6 months and 1 year. We will ask patients to complete a questionnaire regarding their hand function, and we will assess the sensation in the hand.

What are the possible benefits and risks of participating?

We believe this new technique can lead to better healing of the nerve and therefore improve sensation in the affected finger.

Regardless of which method of repair the patient receives, they will have thorough follow up care. However, there is a small risk of infection as we are inserting a foreign device (conduit) into the body. Additionally, the wound may breakdown and require further surgery, and there is a rare risk of allergic reaction.

Where is the study run from?

Queen Elizabeth Hospital Birmingham (UK) (secondary sites currently being sought)

When is the study starting and how long is it expected to run for?

February 2017 to July 2025.

Who is funding the study?

Polyganics (Netherlands)

Who is the main contact?

Dominic Power

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Study website

<http://www.srmrc.nihr.ac.uk/trauma-research-events/connect/>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

209856

Study information

Scientific Title

Conduit Nerve approximation versus Neurorraphy Evaluation of Clinical outcomes Trial

Acronym

CoNNECT

Study objectives

There is no difference in functional outcomes with microscopic neurorraphy, neurorraphy with a conduit as a wrap and a conduit alone bridge across the co-aptation site without sutures in the nerve ends.

Ethics approval required

Old ethics approval format

Ethics approval(s)

West Midlands - Solihull Research Ethics Committee, 28/02/2017, REC reference: 17/WM/0009, IRAS project ID: 209856

Study design

Interventional three-arm randomised controlled trial powered for equivalence

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment, Efficacy

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Acute digital nerve transection injury in the hand

Interventions

The study will enrol participants with traumatic injuries to the digital or common digital nerves within the hand and randomisation in a 1:1:1 ratio for each nerve injury. They will be stratified according to the age group. The power analysis estimates 62 nerves recruited to each group to demonstrate equivalence. 240 nerves will be recruited to allow a drop out of 30% with the modified Weber scale as a primary outcome measure of sensory recovery using static and moving two point discrimination at 12 months.

Each group will receive a different form of microsurgical repair:

1. Direct microsurgical suture
2. Suture with nerve conduits augmentation
3. Nerve conduits apposition with remote suture distal to the injury site

Intervention Type

Device

Pharmaceutical study type(s)

Not Applicable

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Neurolac conduit

Primary outcome measure

Sensory recovery using static and moving two-point discrimination (tactile gnosis) for each repaired nerve. The comparable area on the opposite hand will be tested for static and moving two-point discrimination to act as a baseline for assessment of recovery. These measurements will allow the modified Weber score to be calculated. This will be assessed at weeks 2, 6, 12, 26 and 52.

Secondary outcome measures

The following will be assessed at weeks 2, 6, 12, 26 and 52:

1. Monofilament pressure thresholds (innervation density), assessed using the WEST Monofilaments
2. Upper extremity disability and symptoms, assessed using the Disabilities of the Arm, Shoulder and Hand (DASH) score
3. Self-rated health, assessed using the EQ-5D
4. Nerve irritation, assessed using differential Tinel's sign
5. Pain, assessed using a visual analogue scale (VAS)
6. Cold intolerance, assessed using a VAS
7. Hyperaesthesia, assessed using a VAS
8. Site of repair, measured in mm from the hyponychium of the same digit (the duration of each repair will be recorded)
9. For suture repairs, the quality of the repair will be recorded using the visual grading scale for suture-only nerve repair
10. For common digital nerve repair, the outcome for each digital nerve territory will be recorded

Overall study start date

01/02/2017

Completion date

01/07/2025

Eligibility

Key inclusion criteria

Pre-operative inclusion criteria:

1. Age between 16-75 years
2. Traumatic lesion less than 10 days old
3. Clinical suspicion of a complete traumatic nerve lesion to a sensory nerve between the distal flexor retinaculum and the midpoint of the middle phalanx
4. Ability to consent to the trial and comply with the follow up regime.

Intra-operative inclusion criteria:

1. Verification of a complete traumatic lesion of a sensory nerve
2. Nerve amenable to suture directly without excessive flexion of digit (MCPJ and PIPJ positioning less than 30 degrees of flexion)

Participant type(s)

Patient

Age group

Adult

Lower age limit

16 Years

Upper age limit

75 Years

Sex

Both

Target number of participants

It is estimated that 62 digital nerves will need to be included in each arm of the study (95% confidence, 80% power). In order to compensate for dropouts from the study estimated at 20%, over recruitment is planned with 80 digital nerves in each of the three groups. The aim is to recruit 171 patients during the study period. Recruitment is estimated at 60% of eligible patients based on our experience of recent clinical trials and a patient survey regarding the proposed trial and follow-up requirements. Approximately 300 patients will need to be invited to participate in order to achieve this target

Total final enrolment

240

Key exclusion criteria

Pre-operative exclusion criteria:

1. Wound infection
2. Traumatic amputation
3. Previous history of injury to the nerves in the injured digit

4. Patients diagnosed with peripheral neuropathy
5. Participation in other trials

Intra-operative exclusion criteria:

1. Nerve gap due to segmental loss requiring a graft or conduit
2. Double level injury to the same nerve
3. Severe contamination necessitating a further surgical procedure prior to closure

Date of first enrolment

01/07/2017

Date of final enrolment

01/10/2023

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

The Birmingham Hand Centre

Queen Elizabeth Hospital Birmingham

Surgical Reconstruction and Microbiology Research Centre

Institute of Translational Medicine

Heritage Building

University Hospitals Birmingham NHS Foundation Trust

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B15 2WB

Sponsor information

Organisation

University Hospitals Birmingham NHS Foundation Trust

Sponsor details

Research and Development

Mindelsohn Way

Edgbaston

Birmingham

England
United Kingdom
B15 2WB

Sponsor type

Hospital/treatment centre

Website

<https://www.uhb.nhs.uk/home.htm>

ROR

<https://ror.org/014ja3n03>

Funder(s)

Funder type

Industry

Funder Name

Polyganics

Results and Publications

Publication and dissemination plan

Current publication and dissemination plan as of 11/11/2024:

We are planning to publish in 2025 and after the overall trial is complete - recruitment extended due to COVID. All patients completed final 12 month follow up time point

Previous publication and dissemination plan:

We are planning to publish in 2019 and after the overall trial is complete (summer 2021).

Intention to publish date

01/12/2026

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made 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?
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