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CoNNECT: A study of sutureless nerve repair

Submission date 24/07/2018	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 04/02/2019	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 11/11/2024	**Condition category** Surgery	[_] Individual participant data [X] 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

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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
Mindelsohn Way
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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

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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?

HRA research summary	28/06/2023	No	No