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A clinical trial to develop new ways of measuring nerve healing after injury

Submission date
25/03/2019

Recruitment status
No longer recruiting

Registration date
21/05/2019

Overall study status
Completed

Last Edited
18/09/2023

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Peripheral nerve injuries result in a loss of sensation to crucial areas of the hand. Alongside this, there is a loss of sweating and changes to the skin of the affected area. This study aims to assess whether it is possible to assess these skin changes in nerve-injured patients in order to examine if they can be used to monitor recovery of sensation in patients who have undergone treatment.

Who can participate?
Patients over 18 years old who are attending Wythenshawe Hospital, Department of Plastic Surgery with a nerve injury in their forearm

What does the study involve?
Skin changes are measured using OCT (Optical Coherence Tomography) imaging, a non-invasive device. The researchers also aim to investigate whether detailed three-dimensional ultrasound (similar to pregnancy scans) can be used to monitor nerve regeneration at the operation repair site. This imaging tool is non-invasive can be used to determine how fast the nerve is re-growing and also the volume of the re-growing nerve.

What are the possible benefits and risks of participating?
There will be no effect on the patients' normal care pathway or surgery. There is no anticipated risk to patients. The imaging devices used are non-invasive and do not cause harm to patients.

Where is the study run from?
Wythenshawe Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2018 to August 2022 (updated 06/08/2020, previously: July 2020)

Who is funding the study?
1. British Association Of Plastic Reconstructive And Aesthetic Surgeons
2. Royal College of Surgeons of England

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Scientific

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Additional identifiers

Protocol serial number
40584

Study information

Scientific Title
Novel Outcome measures in Peripheral Nerve injury (OPEN study)

Acronym
OPEN

Study objectives
Will changes in: sweat gland density and epidermal thickness as measured by OCT and volume and growth of the regenerating nerve as measured by high-frequency 3D ultrasound, correspond to changes in current sensory outcome measures (two-point discrimination (2PD), locognosia, Weinstein Enhanced Sensory Test (WEST) monofilament and STI Test) and patient-reported outcome measures (DASH and i-Hand) following peripheral nerve repair.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/01/2019, East Midlands – Nottingham 1 Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; Tel: +44 (0)207 104 8101; Email: NRESCommittee.eastmidlands-nottingham1@nhs.net), ref: 18/EM/0426

Study design
Non-randomized; Interventional; Design type: Screening, Device, Imaging, Active Monitoring

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Peripheral nerve injury

Interventions
There are no study 'interventions' as such, just additional imaging measurements. These are as follows:
Date of surgery (or within 7 days post-op): OCT scanning, high frequency 3D ultrasound scan (Hf, 3D,USS), sensory outcome measures and PROMs
Week 2: OCT scanning, high frequency 3D ultrasound scan (Hf,3D,USS), sensory outcome measures and PROMs
Week 6: OCT scanning, high frequency 3D ultrasound scan (Hf,3D,USS), sensory outcome measures and PROMs
Month 3: OCT scanning, high frequency 3D ultrasound scan (Hf,3D,USS), sensory outcome measures and PROMs
Month 6: OCT scanning, high frequency 3D ultrasound scan (Hf,3D,USS), sensory outcome measures and PROMs
Month 12: OCT scanning, high frequency 3D ultrasound scan (Hf,3D,USS), sensory outcome measures and PROMs

Intervention Type
Other

Primary outcome(s)
Measured at date of surgery (or within 7 days post-op), weeks 2 and 6, and months 3, 6 and 12:
1. Sweat gland density and epidermal thickness measured by Optical Coherence Tomography
2. Regenerative rate and volume of the regenerating nerve measured by high-frequency, three-dimensional ultrasound

Key secondary outcome(s))
Sensory outcome measures:
1. Tactile spatial discrimination measured using 2 Point Discrimination Test at week 1/baseline, week 2/baseline, week 6, months 3, 6 and 12
2. Pressure detection threshold measured using Weinstein Enhanced Sensory Test (WEST) monofilament at week 1/baseline, week 2/baseline, week 6, months 3, 6 and 12
3. Tactile spatial discrimination measured using locognosia at week 1/baseline, week 2/baseline, week 6, months 3, 6 and 12
4. Stereogenesis measured using Shape/Texture Identification Test at months 6 and 12

Motor outcome measures:
1. Individual muscle strength measured using manual muscle testing (MRC Grading) at week 1

/baseline, week 2/baseline, week 6, months 3, 6 and 12
2. Grip strength measured using Jamar Dynamometer at week 1/baseline, week 2/baseline, week 6, months 3, 6 and 12

Patient-Reported Outcome Measures (PROMs):
1. Functional disability and pain caused by nerve injury measured using DASH and i-HAND at week 1/baseline, week 2/baseline, week 6, months 3, 6 and 12

Completion date
04/08/2022

Eligibility

Key inclusion criteria
1. 18 – 80 years old
2. Peripheral nerve injury of ulnar or median nerve (or both) distal to the elbow
3. Having direct, epineural surgical repair within 1 week after injury
4. Capacity to consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
80 years

Sex
All

Total final enrolment
5

Key exclusion criteria
1. Outside of stated age range
2. Outside stated location of injury
3. Nerve gap requiring alternative surgical management
4. Lacks capacity to consent

Date of first enrolment
01/05/2019

Date of final enrolment

03/08/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Wythenshawe Hospital
Manchester University NHS Foundation Trust
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Sponsor information

Organisation
The University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Charity

Funder Name
British Association Of Plastic Reconstructive And Aesthetic Surgeons (BAPRAS)

Funder Name
Royal College of Surgeons of England

Alternative Name(s)
RCS England, RCS ENG, The Royal College of Surgeons of England, RCS

Funding Body Type

Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		13/09/2023	15/09/2023	Yes	No
HRA research summary			28/06/2023	No	No