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Electrical stimulation after nerve repair to enhance regeneration

Submission date	Recruitment status	[ ] Prospectively registered
12/08/2013	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
04/09/2013	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/09/2013	Injury, Occupational Diseases, Poisoning	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Injuries causing nerve damage in the arm and hand are common. In severe cases, outcomes with surgery remain poor. Recently, in animal studies a short period of electrical stimulation applied to injured nerves was shown to improve nerve regeneration. Therefore, we plan to test this new method of treatment to determine whether it is also helpful in humans.

Who can participate?
We aim to recruit 150 adult patients of both genders over the age of 18 years who sustained severe injuries to nerves in the arm and hand.

What does the study involve?
Patients will be randomly allocated to either the control group with surgery alone or to the experimental group with additional electrical stimulation for an hour. Following the treatment, all measurements taken at the start of the study will be re-evaluated every three months for the first year and every six months during the second year. The timing and nature of the evaluation process will be identical in both groups.

What are the possible benefits and risks of participating?
If the additional treatment turns out to the effective, we anticipate that there will be greater functional improvements compared to conventional treatment alone. There are the possible risks of bleeding and infection from the needle electrode. To minimize those risks, the needle will be removed as soon as the stimulation is over.

Where is the study run from?
This single centre study will be run from the Peripheral Nerve Trauma Clinics at the University of Alberta (Canada).

When is the study starting and how long is it expected to run for?
The study started in August 2013 and will run until July 2017.

Who is funding the study?
The Canadian Institute of Health Research.

Who is the main contact?
Dr Ming Chanming
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Contact information

Type(s)
Scientific

Contact name
Dr Ming Chan

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effectiveness of a new treatment for patients with peripheral nerve injuries in the upper limb

Study objectives
1. Nerve regeneration in the arm and digital nerve in the hand can be significantly enhanced when they are combined with post-surgical electrical stimulation.
2. The improved nerve regeneration with post-operative electrical stimulation will result in a significant improvement in hand functions compared with surgery alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Human Research Ethics Board (Biomedical), University of Alberta. Approval date: 8 March 2103. Reference Number: Pro00000973

Study design
Interventional randomised double-blind placebo-controlled single centre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

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

Interventions
Intervention: Post surgical electrical stimulation
Controls: Surgery alone.
Duration: The electrical stimulation will last for 1 hour. Total follow up length is 2 years.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Motor unit number estimation - Nerve conduction studies to determine motor nerve regeneration.
2. Quantitative sensory testing to determine sensory nerve regeneration

All outcomes measured at baseline, 3 months, 6 months, 9 months, 12 months, 18 months, 24 months

Secondary outcome measures
1. Symptom severity scales - Questionnaires to determine change in symptom severity
2. Hand functional evaluation - Hand function tests to determine strength and dexterity

All outcomes measured at baseline, 3 months, 6 months, 9 months, 12 months, 18 months, 24 months

Overall study start date
01/08/2013

Completion date
30/07/2017

Eligibility

Key inclusion criteria
Patients (both male and female over the age of 18 years) with severe injury to the nerves in the upper arm, forearm or hand causing denervation.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Other injuries that would impair hand function.
2. The presence of other neurologic conditions.
3. Cognitive compromise that renders the patients unable to understand and consent to the study.
4. Minors younger than the age of 18.

Date of first enrolment
01/08/2013

Date of final enrolment
30/07/2017

Locations

Countries of recruitment
Canada

Study participating centre
5005 Katz Group Centre
Edmonton
Canada
T5R 2E1

Sponsor information

Organisation
University of Alberta (Canada)

Sponsor details
Research Ethics Office
308 Campus Tower
8625 112 Street
Edmonton
Canada
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Sponsor type
University/education

Website
http://www.ualberta.ca/

ROR
https://ror.org/0160cpw27

Funder(s)

Funder type
Government

Funder Name
Canadian Institute of Health (Canada) Reference number: RMF82496

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration