

Electrical stimulation after nerve repair to enhance regeneration

Submission date 12/08/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 04/09/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 04/09/2013	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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 be 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

5005 Katz Group Centre

University of Alberta

Edmonton

Canada

T5R 2E1

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

ROR

<https://ror.org/0160cpw27>

Funder(s)**Funder type**

Government

Funder Name

Canadian Institute of Health (Canada) Reference number: RMF82496

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration