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Safety study of a spider silk nerve guide for repairing large nerve gaps in humans

Submission date
27/02/2026

Recruitment status
No longer recruiting

Registration date
02/03/2026

Overall study status
Ongoing

Last Edited
02/03/2026

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Peripheral nerves are the nerves outside the brain and spinal cord. They control movement and sensation (such as touch and pain). These nerves can be damaged by trauma or during surgery, especially cancer surgery. When a nerve is cut and there is a large gap between the two ends, it cannot simply be stitched back together. This can result in permanent numbness, weakness, pain and reduced quality of life.
The current standard treatment for large nerve gaps is called an autograft. This involves taking a healthy nerve from another part of the patient's body and using it to bridge the gap. This causes permanent loss of function at the donor site and can lead to complications such as pain, infection and poor wound healing. Recovery is often incomplete.
A new device called SilkAxons™ has been developed to help nerves regrow across large gaps. It is made from spider silk fibres, which act as a scaffold (support structure) to guide nerve growth. The silk is placed inside one of the patient's own veins, which forms a natural tube around it. The silk gradually dissolves over time.
This study aims to find out whether SilkAxons™ is safe to use in humans for repairing large nerve gaps. It will also explore whether standard clinical tests can reliably measure nerve recovery in this setting to help plan larger future studies.

Who can participate?
Patients aged 18 to 55 years scheduled for surgery that will involve cutting a peripheral nerve and creating a large gap (between 3 cm and 10 cm) that cannot be directly repaired with stitches. Examples include nerve biopsy, tumour removal or planned nerve graft procedures.

What does the study involve?
This is a small, single-centre study taking place in Panama. During the planned operation, once the nerve has been cut, the surgeon will:
1. Take a short section of one of the patient's own veins.
2. Insert the SilkAxons™ fibres into the vein.
3. Use this vein-and-silk construct to bridge the nerve gap.
Participants will be followed for 12 months after surgery. Follow-up visits will take place at 1, 3, 6 and 12 months. At these visits, doctors will:
1. Check for any complications or side effects.

2. Assess sensation using touch tests.
3. Assess muscle strength if the nerve controls movement.
4. Perform electrical nerve tests at selected visits.
5. Ask participants to complete questionnaires about pain and overall improvement.
The main aim is to monitor safety, particularly in the first 6 months while the silk device dissolves (expected within about 3 to 4 months).

What are the possible benefits and risks?
This is an early-stage ("first-in-human") study. The main benefit is to help determine whether this new device is safe and suitable for further testing. If successful, it could lead to improved treatments for people with severe nerve injuries in the future.
The device may help guide nerve regrowth and improve recovery, but this cannot be guaranteed. Participants may benefit from close follow-up and monitoring.
Risks include standard surgical risks such as infection, bleeding or poor wound healing. There may also be risks related to vein harvesting or a reaction to the silk implant. In rare cases, further surgery may be needed to remove the device.
Strict safety monitoring procedures are in place. The study will be paused or stopped if significant safety concerns arise.

Where is the study run from?
The Panama Clinic in Panama

When is the study starting and how long will it run?
August 2025 to December 2026

Who is funding and sponsoring the study?
UK Research and Innovation (UKRI) through the Horizon Europe Guarantee scheme

Who is the main contact?
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Contact information

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Public, Scientific

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Additional identifiers

Universal Trial Registration Number
U1111-1323-9544

Study information

Scientific Title
First-in-human safety trial to evaluate the reconstruction of large gap nerve defects in humans using an implanted silk nerve guide

Acronym
NSA1: SilkAxons

Study objectives
To assess the safety of a new peripheral nerve repair device (SilkAxons), and assess the feasibility of assessing large gap nerve regeneration.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/06/2025, Comité de Bioética en Investigación de The Panama Clinic (Centro Pacific Center, Torre A, piso 17 oficina 1714. Calle Ramon H Jurado-ciudad de Panamá, Panama, 00507, Panama; +507 (0)310-2414; comitebioeticatpc@thepanamaclinic.com), ref: EC-CBITPC-144

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control

Uncontrolled

Assignment
Single

Purpose
Device feasibility, Treatment, Safety (First-in-Human)

Study type(s)

Health condition(s) or problem(s) studied
Adults aged 18-55 years who are undergoing a surgical procedure that will generate a large gap (3-10 cm) in peripheral nerve discontinuity (sensory, motor or mixed) that cannot be directly repaired with suturing

Interventions
For adults aged 18-55 years who are undergoing a surgical procedure that will generate a large gap (3-10 cm) peripheral nerve discontinuity (sensory, motor or mixed) that cannot be directly repaired with suturing, for example, from autograft harvesting, nerve biopsy, neuroma or tumour excision. The nerve gap is to be repaired with the appropriate number of SilkAxons devices (a silk scaffold) inserted into an autologous vein graft taken from the surgical field.

Intervention Type
Device

Phase
Phase II

Drug/device/biological/vaccine name(s)
SilkAxons

Primary outcome(s)
1. The safety of using SilkAxonsTM in humans for large gap nerve repair until fully resorbed, measured using the number, type, and severity of device-related adverse events at discharge, 1 month, 3 months and 6 months

2. The safety of using SilkAxonsTM in humans for large gap nerve repair until fully resorbed, measured using the number, type, and severity of all harvest site adverse events at discharge, 1 month, 3 months and 6 months

3. The safety of using SilkAxonsTM in humans for large gap nerve repair until fully resorbed, measured using the incidence of removal of the SilkAxonsTM device to treat complications at discharge, 1 month, 3 months and 6 months

Key secondary outcome(s)
1. The safety of the procedure for implanting SilkAxonsTM inside an autograft donor vein for an extended 1-year follow-up, measured using the number, type, and severity of procedure-related (not directly related to SilkAxons device) adverse events at each follow-up evaluation and planned at 1 month, 3 months, 6 and 12 months, alongside physician standard of care

2. The safety of the procedure for implanting SilkAxonsTM inside an autograft donor vein for an extended 1-year follow-up, measured using the number, type, and severity of all harvest site adverse events at each follow-up evaluation and planned at 1 month, 3 months, 6 and 12 months, alongside physician standard of care

3. The safety of the procedure for implanting SilkAxonsTM inside an autograft donor vein for an extended 1 year follow-up, measured using the incidence of further operations to the target surgical site at each follow-up evaluation and planned at 1 month, 3 months, 6 and 12 months, alongside physician standard of care

4. The feasibility of measuring nerve regeneration after repair in the target nerve (motor, sensory or mixed), measured using a composite of sensory recovery (by static and moving 2-point discrimination and Semmes-Weinstein monofilament testing) and pain evaluation (via a visual analog scale/Spanish Visual Pain Numeric [SPVN] scale), at discharge, 1, 3, 6 and 12 months

5. The feasibility of measuring nerve regeneration after repair in the target nerve (motor, sensory or mixed), measured using a composite of motor recovery (as measured by Medical Research Council Classification [MRCC] for motor recovery) and pain evaluation (via a visual analog scale/SPVN) at discharge, 1, 3, 6 and 12 months

6. The feasibility of measuring nerve regeneration after repair in the target nerve (motor, sensory or mixed), measured using Nerve Conduction Studies (NCS) at 3, 6 and 12 months

7. The feasibility of measuring nerve regeneration after repair in the target nerve (motor, sensory or mixed), measured using electromyography (EMG) only if mixed or motor nerve treated at 3, 6 and 12 months

8. The impact on patient-reported outcome measures and quality-of-life improvements, measured using quality of life as measured by Patient Global Impression of Change (PGIC) questionnaire and SPVN pain score at 1, 3, 6 and 12 months

Completion date
25/12/2026

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the trial
2. Between 18 and 55 years of age
3. Patient requires surgery that would require planned transection of a peripheral nerve, generating a “large gap” defect between 3 and 10 cm (e.g. nerve biopsy, autograft donor or tumour excision)
4. Transected nerve can be reconstructed at same operation as defect created
5. Sufficient distal skin sensation or measurable motor function present for transected nerve to be able to record effect of transection and subsequent recovery
6. In the Investigator’s opinion, is able and willing to comply with all trial requirements
7. Willing to attend sufficient follow-up assessments to determine the outcomes of the repair and comply with site-specific postoperative care procedures

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
All

Total final enrolment
5

Key exclusion criteria
1. Their medical history includes disorders known to affect the peripheral nervous system (e.g., diabetes mellitus, chronic heavy alcohol use, toxic nerve lesions, polyneuropathy)
2. Their presentation includes any additional injury that could compromise nerve regeneration (e. g., vascular insufficiency to the harvested lower limb)
3. They are known to have a condition, which the Investigator believes may make implementation /interpretation of the protocol or results difficult
4. They have had previous conditions of the affected area that could affect the healing of the actual nerve injury
5. They have been treated with immunosuppressive or antineoplastic agents within 30 days prior to the enrolment
6. Known to be HIV positive from their medical history
7. Participated in another clinical investigation using an investigational new drug or device within 30 days prior to enrolment into this investigation
8. Uncooperative or unsuitable subject (e.g., language barrier, strong suspicion of inability to adhere to follow-up schedule)
9. Suspected or documented allergy to silk
10. Patient is pregnant, lactating, or intends to become pregnant during the study.
11. Medical history of previous vein stripping procedures at the intended surgical site
12. Planned nerve to undergo transection has no clear sensory distribution or measurable motor function based on clinical knowledge and examination

Date of first enrolment
20/08/2025

Date of final enrolment
13/12/2025

Locations

Countries of recruitment
Panama

Study participating centre
The Panama Clinic
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Panama

Sponsor information

Organisation
Newrotex Limited

Funder(s)

Funder type

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available