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Spinal accessory nerve stimulation during neck dissection (SANE)

Submission date
07/08/2026

Recruitment status
Not yet recruiting

Registration date
07/10/2026

Overall study status
Ongoing

Last Edited
07/10/2026

Condition category
Cancer

[X] 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
People with head and neck cancer sometimes need an operation called a neck dissection to remove lymph nodes from the neck. During this operation, a nerve called the spinal accessory nerve can be stretched or injured. This nerve helps control shoulder movement, and injury can lead to shoulder pain, weakness and difficulty moving the arm. These problems can persist for many months after surgery and can affect everyday activities and ability to work.
Research suggests that applying a small electrical current to an injured nerve during surgery may help the nerve recover. Previous studies have used 60 minutes of electrical stimulation, but this may be difficult to introduce routinely because of the additional operating time. Research suggests that a shorter period of 10 minutes may also be beneficial.
The SANE study is a small pilot study. Its main aim is not to determine whether the treatment works, but to find out whether a larger study comparing 10 minutes of nerve stimulation with standard care can be successfully carried out in the NHS. We will assess whether patients can be recruited and followed up, whether the treatment can be delivered as planned, and whether it is acceptable to the surgical team.

Who can participate?
We aim to recruit 14 adults aged over 18 years with head and neck cancer who are due to have a neck dissection as part of treatment intended to cure their cancer. Participants must be able and willing to provide informed consent.
People will not be able to take part if they have previously had a neck dissection, have existing neurological or shoulder problems, have an implanted electrical device such as a pacemaker, or if the spinal accessory nerve or trapezius muscle needs to be removed during surgery.

What does the study involve?
Participants will be randomly allocated to one of two groups. One group will receive their usual NHS care. The other group will receive usual NHS care plus 10 minutes of electrical stimulation of the spinal accessory nerve during their neck dissection. The stimulation is given while the participant is under general anaesthetic. Participants will not know which group they have been allocated to.
Before surgery, participants will complete questionnaires about their shoulder function and quality of life and undergo tests of shoulder movement and nerve function. Blood samples will

also be collected to investigate biological factors that may be related to nerve injury and recovery.
Participants will be followed up at 3, 6 and 12 months after surgery. The shoulder and nerve assessments and questionnaires will be repeated at these visits. Wherever possible, study visits will take place alongside routine hospital appointments to reduce inconvenience.
Each participant is expected to be involved in the study for approximately 15 months, from initial telephone screening until the final 12-month follow-up.

What are the possible benefits and risks of participating?
As this is a pilot study, it is not designed to show whether nerve stimulation improves shoulder function. Participants who receive nerve stimulation may experience improved nerve recovery and shoulder function, but this cannot be guaranteed. All participants may benefit from the additional monitoring and assessments provided during the study. The information collected will help researchers design a larger trial and may help improve care for future patients undergoing neck dissection.
Nerve stimulation is considered low risk, and previous studies have not reported treatment-related nerve injury or damage to surrounding tissues. For participants receiving stimulation, the procedure may slightly increase the length of the operation and time under general anaesthetic. Blood tests may cause temporary discomfort, bruising or light-headedness. Tests of nerve and shoulder function may cause mild discomfort or tiredness, and some questions about health and wellbeing may be upsetting. Participants can take breaks or decline to answer questions if they wish.

Where is the study run from?
The study is being conducted at Churchill Hospital, Oxford University Hospitals NHS Foundation Trust, Oxford, UK. It is a single-centre study.

When is the study starting and how long is it expected to run for?
The study is expected to start on 1 October 2026. Participant recruitment is planned from 1 January 2027 to 1 July 2027.
Participants will be followed for 12 months after surgery. The overall study is expected to run until 1 March 2030, allowing time for completion of follow-up, data collection, data checking and analysis. The study will be considered complete when the final participant's follow-up data have been entered and all outstanding data queries have been resolved.

Who is funding the study?
The study is funded by ORACLE Head & Neck Cancer UK.

Who is the main contact?
Mr Akira Wiberg, akira.wiberg@ndorms.ox.ac.uk

Contact information

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Additional identifiers

Integrated Research Application System (IRAS)
359693

Central Portfolio Management System (CPMS)
75510

Study information

Scientific Title
Spinal accessory nerve stimulation during neck dissection (SANE): a randomised, single-blind, single-centre external pilot study

Acronym
SANE

Study objectives
To assess the feasibility, fidelity and acceptability of delivering 10 minutes of intra-operative spinal accessory nerve stimulation during neck dissection within an NHS setting, to inform the design of a definitive randomised controlled trial.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 23/03/2026, University of Oxford Research Governance, Ethics & Assurance, Joint Research Office (University of Oxford, Boundary Brook House, Churchill Drive, Headington, Oxford, OX3 7GB, United Kingdom; no telephone number provided; rgea.sponsor@admin.ox.ac.uk), ref: 26/SC/0259

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Single

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Head and Neck Cancer

Interventions
Study design:
This is a single-centre, parallel-group, two-arm, single-blind, randomised controlled external pilot study. The trial will evaluate the feasibility of delivering intra-operative spinal accessory nerve stimulation for 10 minutes, compared with standard care alone, in patients undergoing neck dissection. The study will be conducted at a tertiary NHS surgical centre in England.

Blinding:
Participants will be blinded to their treatment allocation. Owing to the intra-operative nature of the intervention, outcome assessors, research staff, and members of the surgical team will not be blinded.

Eligibility and recruitment:
All adults aged ≥18 years scheduled for curative-intent neck dissection will be screened for eligibility. Screening logs will document the numbers of patients assessed, eligible, excluded, and enrolled. Eligible patients attending head and neck cancer clinics at Churchill Hospital, across Plastic Surgery, ENT, and Oral & Maxillofacial Surgery, will be identified by the clinical team and approached by a research team member to provide informed consent.

Randomisation:
Participants will be randomised via a secure web-based system to one of two groups (control or 10-minute stimulation). Allocation will be stratified by age, sex, extent of neck dissection, and receipt of pre-operative chemotherapy.

Baseline assessments:
Following randomisation, baseline measures will include:
1. Demographics
2. Neck Dissection Impairment Index (NDII)
3. Shoulder Pain and Disability Index (SPADI)
4. Goniometry (shoulder range of motion)
5. Neurophysiological assessment of the spinal accessory nerve
6. Health-related quality of life: EORTC QLQ-C30, QLQ-H&N35, and EQ-5D-5L
7. Blood sample for genotyping of Val66Met (rs6265) BDNF polymorphism and NfL measurement

Intervention:
Treatment allocation will be disclosed to the surgical team on the day of surgery. In the intervention group, electrical stimulation will be delivered intra-operatively by a trained surgeon in collaboration with a research team member, in accordance with a standard operating procedure. In the intervention group, electrodes will be applied directly to the spinal accessory nerve for 10 minutes of stimulation.
Participants randomised to the control group will receive standard care, and their surgical procedure will be conducted as per routine practice. Electrodes will not be applied to the spinal accessory nerve.

Operative duration (knife-to-skin to closure) will be recorded, and intervention fidelity will be documented using a standardised checklist. All participants will receive standard post-operative care, including physiotherapy and routine surgical follow-up.

Follow-up assessments:
Participants will be followed at 3, 6, and 12 months post-operatively, coordinated with routine clinical appointments. At each time point, outcome measures collected at baseline (excluding the blood sample) will be repeated, together with a global patient-reported rating of change in shoulder function.
Data will be entered directly into a secure REDCap database. Upon completion of the feasibility study, all participants will be invited to complete a brief questionnaire regarding their experience of taking part in the study.

Feasibility outcomes:
Feasibility will be assessed using:
1. Recruitment and retention rates
2. Compliance with intervention delivery and follow-up assessments
3. Completeness of data collection
4. Screening logs to capture eligibility and reasons for non-participation

Qualitative sub-study:
A nested qualitative sub-study will explore the acceptability of the intervention to the surgical team. Six members of the operative and anaesthetic teams, two surgeons, two anaesthetists, and two scrub nurses or equivalent staff, will each participate in a one-hour semi-structured interview to provide qualitative insights into the feasibility of the 10-minute stimulation protocol.
A deductive theory driven approach using the Sekhon's TFA will be used to structure analysis.

Intervention Type
Other

Primary outcome(s)
1. Recruitment feasibility, including the number of potentially eligible and eligible patients, proportion consenting and proportion successfully randomised measured using screening and recruitment logs and electronic case report forms (eCRFs) at screening and randomisation

Key secondary outcome(s)
1. Proportion of randomised participants receiving their allocated treatment measured using the study eCRF and intervention record on the day of surgery
2. Participant retention measured as the proportion of participants attending scheduled follow-up visits using study attendance records and eCRFs at baseline, 3 months, 6 months and 12 months
3. Outcome-measure completeness measured as the proportion of participants completing each scheduled outcome assessment using study eCRFs and REDCap records at baseline, 3 months, 6 months and 12 months
4. Operative duration from knife-to-skin to wound closure measured using prospective recording by the research associate during the operative procedure on the day of surgery
5. Participant's perceived treatment allocation measured using Bang's Blinding Index at 12 months
6. Intervention fidelity, including completion of or deviation from each predefined component of the stimulation procedure, measured using the SANE Intervention Fidelity Checklist completed

by the research associate during intervention delivery on the day of surgery
7. Surgical team members' experiences and perceptions of intervention acceptability, including barriers and facilitators to delivering the intervention, measured using a semi-structured interview with a topic guide informed by Sekhon's Theoretical Framework of Acceptability following participation in delivery of the 10-minute stimulation intervention
8. Patient-reported neck and shoulder impairment measured using the Neck Dissection Impairment Index (NDII) questionnaire at baseline, 3 months, 6 months and 12 months
9. Shoulder pain and functional disability measured using the Shoulder Pain and Disability Index (SPADI) questionnaire at baseline, 3 months, 6 months and 12 months
10. Shoulder range of motion measured using goniometry at baseline, 3 months, 6 months and 12 months
11. Patient-reported change in shoulder function measured using the 15-point Global Rating of Change in shoulder function at 3 months, 6 months and 12 months
12. Spinal accessory nerve and trapezius function, including compound motor action potential amplitude, motor conduction velocity and trapezius motor unit number estimation, measured using spinal accessory nerve neurophysiology/nerve conduction studies at baseline, 3 months, 6 months and 12 months
13. Patient-reported cancer-related health-related quality of life measured using the EORTC QLQ-C30 questionnaire at baseline, 3 months, 6 months and 12 months
14. Patient-reported head and neck cancer-specific health-related quality of life measured using the EORTC QLQ-H&N35 questionnaire at baseline, 3 months, 6 months and 12 months
15. Patient-reported generic health status and health-related quality of life measured using the EQ-5D-5L questionnaire at baseline, 3 months, 6 months and 12 months
16. BDNF Val66Met (rs6265) genotype measured using PCR-based genotyping of a blood sample at the baseline/pre-operative assessment
17. Blood neurofilament light chain (NfL) concentration measured using laboratory NfL measurement of a blood sample pre-operatively and at 24 hours post-operatively

Completion date
01/03/2030

Eligibility

Key inclusion criteria
Patients in primary study:
1. Competent adult patients with head and neck cancer who are scheduled to undergo neck dissection including level 2b +/- level 5
2. Willing and able to give informed consent for participation in the trial.
3. Age >18 years, male or female
4. Surgery is intended to be curative

Healthcare professionals in qualitative sub-study:
1. Surgical consultant, surgical registrar, anaesthetic consultant, anaesthetic registrar, scrub nurse or operating department practitioner involved in the 10-min stimulation arms
2. Willing and able to give consent

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Patients in primary study:
1. Previous neck dissection
2. Intra-operative resection of spinal accessory nerve or trapezius
3. Pre-existing neurological or shoulder dysfunction
4. Implanted electrical device e.g. pacemaker

Healthcare professionals in qualitative sub-study:
1. Lack of English language proficiency

Date of first enrolment
01/01/2027

Date of final enrolment
01/07/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Oxford University Hospitals NHS Foundation Trust
Churchill Hospital Old Road, Headington
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Sponsor information

Organisation

University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
Oracle Head and Neck Cancer UK Limited

Results and Publications

Individual participant data (IPD) sharing plan
he datasets generated during and/or analysed during the current study are/will be available upon request from Mr Akira Wiberg, akira.wiberg@ndorms.ox.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.0	22/03/2026	06/10/2026	No	Yes