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Safety and performance of the Nurotron CS-30A cochlear implant system in adults with hearing loss

Submission date
10/06/2026

Recruitment status
Recruiting

Registration date
15/06/2026

Overall study status
Ongoing

Last Edited
11/06/2026

Condition category
Ear, Nose and Throat

[_] 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
Some adults have severe to profound hearing loss in both ears and do not gain enough benefit from hearing aids. A cochlear implant is a medical device that can help people hear sounds by directly stimulating the hearing nerve.

This study aims to look at how safe the Nurotron CS-30A cochlear implant system is and how well it helps adults hear following implantation. The information collected will help doctors understand how the device performs when used in routine clinical practice.

Who can participate?
Adults under 18 years and older with sever to profound hearing loss in both ears may be able to take part. Participants must meet the usual medical criteria for cochlear implantation in the ear to be implanted. People will be assessed to confirm whether they are suitable before joining the study.

What does the study involve?
All participants in the study will receive a cochlear implant as part of their treatment. The implant surgery will be performed by experienced specialists.

Before and after implantation, participants will attend follow-up visits at the study centre. During these visits, hearing tests will be carried out and participants will be asked to complete questionnaires about their hearing and daily life. Participants will be followed for up to 12 months after implantation.

What are the possible benefits and risks of participating?
Based on previous clinical use of cochlear implants, many participants are expected to experience improvements in hearing and hearing-related quality of life after implantation. However, the degree of improvement varies between individuals and cannot be guaranteed.

As with any operation and implanted medical device, there are possible risks. These include risks related to surgery and potential device-related problems. Participants will be monitored throughout the study to check for any safety issues.

Where is the study run from?
This study is managed from specialist cochlear implant centres in Europe and will take place at centres in the United Kingdom, Germany, Spain, and Poland.

When is the study starting and how long is it expected to run for?
May 2026 to May 2027

Who is funding the study?
The study is funded by Nurotron Global SARL

Who is the main contact?
Professor Dan Jiang: dan.jiang@gstt.nhs.uk

Contact information

Type(s)
Principal investigator, Scientific, Public

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Integrated Research Application System (IRAS)
347371

Study information

Scientific Title
Evaluation of safety and effectiveness the Nurotron CS-30A cochlear implant system in adults

Study objectives
To establish the benefits of the Nurotron CS-30A Cochlear Implant System in adults with severe-to-profound bilateral sensorineural hearing loss, including improvements in hearing performance, speech perception, and hearing-related quality of life, while monitoring safety through detailed adverse event assessment.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 16/01/2025, Dulwich Research Ethics Committee (Dulwich Research Ethics Committee, Health Research Authority, 2nd Floor, 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 20 7104 8000; dulwich.rec@hra.nhs.uk), ref: 24/LO/0903

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Pre-market clinical investigation

Study type(s)

Health condition(s) or problem(s) studied
Post-lingual severe-to-profound bilateral sensorineural hearing loss in adults

Interventions
This is a prospective, multicentre, single-arm interventional study. Participants will undergo implantation with the Nurotron CS-30A Cochlear Implant System in the ear selected according to study inclusion criteria. The device consists of an implantable internal unit and an external speech processor that converts sound into electrical stimulation of the auditory nerve.

Following baseline assessments (aided and unaided hearing thresholds, speech perception tests, and quality-of-life questionnaire), participants will undergo cochlear implantation surgery. The external speech processor will be activated approximately 1–6 weeks post-surgery, with device fitting, programming, and rehabilitation sessions provided using the NuroSound system.

Outcomes will be assessed at follow-up visits at 1, 3, 6, and 12 months after activation. Primary efficacy endpoints include aided word and sentence recognition in quiet and in noise, and secondary endpoints include hearing-related quality of life. Safety is monitored through adverse event reporting, adjudicated by an independent Data Safety Monitoring Board and Clinical Event Committee.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
CS-30A Cochlear Implant System

Primary outcome(s)
1. Word recognition in quiet measured using Percentage of words correctly understood in a validated monosyllabic word recognition test administered via loudspeaker at 65 db SPL at Baseline, 1 month, 3 months, and 6 months post-activation

2. Device-related serious adverse events measured using Accumulated incidence of device-related adverse events triggering surgical reintervention, adjudicated by independent DSMB and Clinical Event Committee at Baseline through 12 months post-implantation

Key secondary outcome(s))
1. Sentence recognition in quiet measured using Percentage of words correctly understood in validated sentence test lists, presented via loudspeaker at 65 dB SPL at Baseline, 1 month, 3 months, and 6 months post-activation

2. Sentence recognition in noise measured using Percentage of words correctly understood in sentence test lists in noise at +5/+10 dB SNR at Baseline, 1 month, 3 months, and 6 months post-activation

3. Pure-tone audiometry thresholds measured using Aided acoustic pure-tone thresholds (dB HL) in the implanted ear at Baseline, 1 month, 3 months, and 6 months post-activation

4. Hearing related quality of life measured using quality of life questionnaire at Baseline and 3 months post-activation

5. All adverse events measured using Number and percentage of participants reporting each adverse event, including onset, severity, duration, course of action, and resolution; summarized by type and incidence. at Baseline through 12 months post-implantation

Completion date
30/11/2027

Eligibility

Key inclusion criteria
1. 18 years or older
2. Post-lingual onset of severe sensory neural hearing loss (from 6 years old or older)
3. Local language proficiency
4. In the ipsilateral ear: unaided acoustic pure-tone thresholds of ≥ 50 dB HL at 500 Hz, ≥ 60 dB HL at 1000 Hz, ≥ 70 dB HL by 2000, 4000 and 8000 Hz; Marginal hearing aid benefit, defined as word recognition score of ≤ 50% in the best-aided condition at 65dB SPL without lip-reading; Duration & performance situation at base-line, sensory neural loss level ≥ 3 months stable (preferably ≥ 6 months) unless risk of imminent obliteration

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Previous ear surgery that could compromise the inner ear
2. Indication of a central auditory lesion or compromised auditory nerve (ideally confirmed by preoperative MRI)
3. Cochlear malformation or obstruction that would preclude full insertion of electrode array
4. Presence of additional disabilities that would prevent or interfere with participation in the required study procedures;
5. Medical or physiological conditions that contraindicate surgery or impact the ability to manage an implanted device or the study related procedures (e.g. silicone allergy)
6. Presence of magnetically adjustable CSF shunts or any active implantable medical device in the study candidate at the time of informed consent signature

Date of first enrolment
12/05/2026

Date of final enrolment
15/11/2026

Locations

Countries of recruitment
United Kingdom

England

Germany

Poland

Spain

Study participating centre

Guy's and St Thomas' NHS Foundation Trust
St Thomas' Hospital
Westminster Bridge Road
London
England
SE 1 7EH

Study participating centre
Universitaetsklinikum Freiburg
Hugstetter Strasse 55
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Germany
79106

Study participating centre
University of Valencia
Avinguda Blasco Ibanez, 13
Nivell 3
Valencia
Spain
46010

Study participating centre
Warsaw Institute of Physiology and Pathology of Hearing
Mokra 17
Warsaw
Poland
05-830

Sponsor information

Organisation
Nurotron Global SARL

Funder(s)

Funder type

Funder Name
Nurotron Global SARL

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available