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Ultra-long-term EEG monitoring in people with intellectual disabilities

Submission date
30/10/2024

Recruitment status
Recruiting

Registration date
03/03/2025

Overall study status
Ongoing

Last Edited
03/03/2025

Condition category
Nervous System Diseases

[ ] 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
Many people with intellectual disabilities (PwID) experience seizures, but diagnosing and monitoring them can be challenging. Electroencephalography (EEG) is commonly used to assess seizures, but traditional EEG monitoring can be uncomfortable and difficult for PwID. UNEEG Medical has developed a small implantable device, SubQ, which is placed under the skin on the scalp to track brain activity continuously without requiring hospital stays.
This study aims to evaluate how well the SubQ device detects seizures in people with mild to moderate intellectual disabilities. Researchers will assess its safety, impact on quality of life, and effects on behaviour. The study will also explore the experiences of carers and clinicians, as well as the potential cost-effectiveness of the technology.

Who can participate?
Adults (aged over 18 years) diagnosed with mild to moderate intellectual disabilities and epilepsy or suspected seizures who have the capacity to provide consent

What does the study involve?
Participants will have the UNEEG SubQ device implanted under their scalp. EEG data will be collected continuously and compared with seizure diaries. Behaviour and quality of life will be assessed using surveys before implantation, immediately after, and at 3 and 6 months. Carers and healthcare professionals will take part in focus groups to discuss their experiences with the device.

What are the possible benefits and risks of participating?
Potential benefits:
1. More accurate seizure detection, reducing the risk of missed or misdiagnosed seizures
2. Improved understanding of seizure-related behaviours in PwID
3. Potential for better treatment planning and management
Potential risks:
1. Minor surgical risks associated with implantation
2. Possible discomfort or irritation from the implanted device

Where is the study run from?
Plymouth and Cornwall NHS Trusts (UK)

When is the study starting and how long is it expected to run for?
January 2024 to May 2026

Who is funding the study?
NHS England Small Business Research Initiative (SBRI) (UK)

Who is the main contact?
Prof. Rohit Shankar

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
347327

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 64835, SBRIH20P2011

Study information

Scientific Title

Acceptability and impact of ultra-long-term subcutaneous EEG monitoring in people with epilepsy and intellectual disability

Study objectives
This feasibility study assesses whether a research project can be successfully conducted. In this case, objectives are used instead of hypotheses because the study explores feasibility rather than tests specific cause-and-effect relationships.

The main aim of this study is to determine whether the 24/7 EEG SubQ can be accepted and used as a seizure detection tool to improve clinical care, quality of life, and challenging behaviour for PwID and epilepsy.

To achieve this aim, the study has the following objectives:
1. To assess the acceptability and safety of the 24/7 EEG SubQ for people with mild to moderate moderate to profound ID
2. To compare seizure detection in the 24/7 EEG SubQ to standard seizure diaries
3. To determine the impact of the 24/7 EEG SubQ Solution feedback on the clinical management of patients
4. To determine the impact of the 24/7 EEG SubQ on patients' quality of life and behaviour
5. To assess user satisfaction for family members, carers, and healthcare professionals
6. To identify strategies and factors supporting the successful implementation of the 24/7 EEG SubQ in this population
7. To evaluate the perceived utility of the 24/7 EEG Sub Q by carers and clinicians in reducing medication for patients and differentiating between challenging behaviors and seizures

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/10/2024, North West - Greater Manchester South Research Ethics Committee (3 Piccadilly Place, Manchester, M1 3BN, UK; +44 (0)207 104 8014, +44 (0)2071048065; gmsouth.rec@hra.nhs.uk), ref: 24/NW/0300

Study design
Observational; Design type: Cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Epilepsy and intellectual disability

Interventions
Study procedure and data collection:
For individual participants, the study will last for approximately 7 months, with a 6-month period of having the SubQ device implanted and actively capturing EEG data. There will be 7 key visits for participants. Visit 1 will be the initial inclusion assessment; if the patient is determined to have the capacity to provide consent, and they do so, they will be provided with a dummy device to trial. This is the same external component as the real device but does not capture any data. They will be asked to wear it for 1-2 weeks to assess tolerability. A researcher will follow up with the carer every few days to identify any issues. Visit 2 will confirm inclusion and collect demographic and baseline data around quality of life (HONOS-ID) and behaviour (Aberrant Behaviour Checklist). Visit 3 will consist of the implantation of the SubQ electrode. Visit 4 will capture the same baseline data post-implantation and Visits 5 and 6 will capture the same data at 3- and 6-months post-implantation. Visit 6 will also capture quantitative and qualitative perceptions of the device (via the System Usability scale and UNEEG device questionnaires and focus groups). Visit 7 will be the explantation of the device. Adverse events will be recorded throughout and managed in the best interests of the patient.

Data analysis:
During the 6-month implantation period, EEG data will be analysed, annotated and provided to patients' healthcare professional on a monthly basis for clinical use. Seizure diaries will also be collected for the months prior to and post-implantation to compare with the EEG data in terms of seizure identification. Quality of life and behaviour will be compared across the four data collection points using repeated-measures ANOVA (or a non-parametric alternative, if needed). Descriptive statistics will be used to evaluate the usability, satisfaction, and perceived impact measures (SUS and UDQs). Semi-structured focus groups will be coded by two investigators using thematic analysis to assess how seizure monitoring is achieved before and after implantation, how PwID are tolerating the device, how carers are using it, and how clinicians use the data coming from the device. The qualitative semi-structured focus groups will be evaluated using thematic analysis.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Participants’ acceptability of real-world implementation with 24/7 EEG SubQ Solution:
1. Adherence: participants’ percentage wear time with 24/7 EEG SubQ, across the study period of 6 months
2. Usability: average score at 6 months (before explantation) on System Usability Scale (SUS)
3. Qualitative results from semi-structured focus groups measured at 6 months
Timepoint(s): 6 months

Secondary outcome measures
1. Safety: number of adverse events related to the use of the device (adverse device effect [ADE]) during the study period

2. Diagnostic accuracy: within-participant correlation between seizure counts per month from participant-reported seizure diary and occurrences per month (derived from EEG expert review and annotation of 24/7 EEG SubQ EEG data), across the 6 months of the study
3. Quality of life measured using HoNOS-ID at V1 (before implantation), 3 and 6 months (before explantation)
4. Behaviour changes measured using Aberrant Behavior Checklist at V1 (before implantation), 2 and 6 months (before explantation)
5. Stakeholder experience (feasibility) measured using qualitative semi-structured focus groups with PwID/family members/carers at V1 (before implantation), 2 and 6 months
6. Diagnostic accuracy: comparison of retrospective seizure diary and seizure diary data reported across the study period
7. Impact on clinical decisions measured using UNEEG Device Questionnaire –'HCP Epilepsy management plan', 'HCP Management', 'HCP Insight' and 'HCP Communication' filled out after each consultation and feedback visit
8. Healthcare provider insights measured using UNEEG Device Questionnaire - 'HCP Insight' at 6 months (before explantation)
9. HCP communication measured using UNEEG Device Questionnaire 'HCP Communication' at 6 months (before explantation)
10. Potential of 24/7 EEG SubQ Monitoring measured using UNEEG Device Questionnaire 'Potential of 24/7 EEG SubQ at 8 months (before explantation)
11. Ease of use measured using UNEEG Device Questionnaire 'PWE Ease of use' at 6 months (before explantation)
12. Impact on everyday life measured using UNEEG Device Questionnaire 'PWE Everyday life' at 6 months (before explantation)
13. Number of device deficiencies across the study period (6 months) provided by UNEEG Medical

Overall study start date
16/01/2024

Completion date
31/05/2026

Eligibility

Key inclusion criteria
PwID:
1. Adults over 18 years old
2. Clinical diagnosis of epilepsy, considered pharmacoresistant
3. Clinical diagnosis of mild to moderate ID based on DSM/ICD classification
4. Patient has the capacity to consent and consents to participate
5. Able to tolerate the dummy device (device worn for at least 40% of a 1-2 week test period)

Family member/carer:
1. Family member/carer is willing to keep a routine seizure diary for the course of the study
2. Retrospective seizure diary data available for the proceeding last 6 months
3. According to a family member, carer, or clinical record, the participant is having at least monthly 'episodes of interest' (it may be unclear whether these are epileptic or behavioural episodes)
4. Agree to participate in the study, support study activities and comply with these

Healthcare professional:
1. PwID recommended by their epileptologist for long-term EEG monitoring Agree to participate in the study, support study activities and comply with these

Participant type(s)
Patient, Health professional, Carer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 10; UK Sample Size: 10

Key exclusion criteria
PwID:
1. Using cochlear implant(s)
2. Established current diagnosis of psychogenic non-epileptic attacks (dissociative seizures) without any epileptic seizures
3. Frequent vigorous involuntary movements (eg. chorea, athetosis) or frequent parasomnias with major motor components (eg. sleepwalking, night terrors)
4. Participants involved in therapies with medical devices that deliver electrical energy into the area around the implant
5. Participants at high risk of surgical complications, such as active systemic infection and haemorrhagic disease
6. Participants who are allergic to the local anaesthetics used during implantation
7. Females of childbearing potential who are pregnant or intend to become pregnant throughout the study
8. Participants who have an infection at the site of device implantation
9. Participants who operate MRI scanners or are planning to have an MRI scan during the study period
10. Participants with a profession/hobby that includes activity imposing extreme pressure variations (e.g. diving or parachute jumping). NB: diving/snorkelling is allowed to 5 meters of depth
11. Participants with a profession/hobby that includes activity imposing an unacceptable risk for trauma against the device or the site of implantation (e.g. martial art or boxing)
12. Any other serious medical condition that in the opinion of the Chief Investigator would be incompatible with participation in the study

Date of first enrolment
01/11/2024

Date of final enrolment
31/05/2026

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
Cornwall Partnership NHS Foundation Trust
Carew House
Beacon Technology Park
Dunmere Road
Bodmin
United Kingdom
PL31 2QN

Study participating centre
The Royal Wolverhampton NHS Trust
New Cross Hospital
Wolverhampton Road
Heath Town
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United Kingdom
WV10 0QP

Study participating centre
Cardiff & Vale University Lhb
Woodland House
Maes-y-coed Road
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CF14 4HH

Study participating centre
University Hospitals Plymouth NHS Trust
Derriford Hospital
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Sponsor type
University/education

Website
https://www.plymouth.ac.uk/

ROR
https://ror.org/008n7pv89

Funder(s)

Funder type
Government

Funder Name
NHS England

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2026

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date (September 2025)

IPD sharing plan summary

Data sharing statement to be made available at a later date