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Measuring brain activity by in-ear electrodes in hospitalised patients

Submission date 07/02/2024	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 07/02/2024	**Overall study status** Completed	
Last Edited 12/12/2024	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Clinical electroencephalography (EEG) is an important test in the care of many patients in hospital – from people who are mildly confused, or those seizures or having “funny turns”, to those who are completely unresponsive. Clinical EEG safely and without harm records “brain waves” (the electrical activity of the brain) from about 20 sensors, called electrodes, temporarily stuck to the scalp with glue or paste. A clinical EEG takes about 15 minutes to set up and 30 minutes to record.
By studying the brain waves recorded from an EEG, a specialist can try and work out what is happening in the brain to cause a patient’s problem. However, EEG is poorly available in hospitals, needing expensive equipment and specialists to record and interpret.
In this study the researchers are interested in making a new kind of EEG recording device which can simply record electrical brain activity from within the ear canal, and without the need for glue or paste. This could make EEG far more available and easier to use because such a device could be quickly and easily inserted without the need for expensive equipment, scalp electrodes, or specialist training.
However, to understand if such a future device is possible, the researchers first need to record “in-ear” EEG signals, i.e., via electrodes not placed on the scalp as normal, but rather placed in the ear canals using an 'ear plug' style electrode built into a soft ear plug. Then, at the same time, the researchers want to record standard clinical EEG from the scalp, and then later compare the two recordings.

Who can participate?
Any patient aged 18 years and over referred to an inpatient EEG

What does the study involve?
During the standard clinical EEG, the researchers will additionally record from the ear canals using a safe and harmless in-ear EEG electrode/sensor. The clinical EEG records from electrodes attached to the skull using glue or paste. The recordings are obtained by an “ear plug” device inserted into the ears at the same time. The in-ear electrodes are single-use only.

What are the possible benefits and risks of participating?
The researchers do not foresee any side effects or disadvantages to taking part in this study.

They have used the same in-ear recording electrodes in many healthy human participants before and they have not reported any problems.
Although unlikely, is possible the in-ear EEG electrodes may cause minor discomfort, just as any ear plug or hearing aid around the ear might. If the patient reports or shows any pain or discomfort, the researchers will remove the in-ear EEG electrode and stop the in-ear EEG recording, but the clinical EEG will carry on as planned, so taking part in the study will not have any negative effects on clinical care.
The study will not have any direct benefit. It is hoped that the information obtained might lead to the development of an in-ear EEG device, which in turn can improve the treatment of people who would benefit from EEG recordings, such as those with impaired consciousness, seizures, and other brain disorders.

Where is the study run from?
Imperial College London (UK)

When is the study starting and how long is it expected to run for?
January 2023 to June 2025

Who is funding the study?
UK Research and Innovation

Who is the main contact?
Dr Gregory Scott, gregory.scott99@imperial.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Gregory Scott

ORCID ID
https://orcid.org/0000-0001-8063-5871

Contact details
UK Dementia Research Institute Care Research and Technology Centre
Floor 9 Sir Michael Uren Hub
Imperial College London, White City Campus
86 Wood Lane
London
United Kingdom
W12 0BZ
+44 (0)20 7589 5111
gregory.scott99@imperial.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
324099

Central Portfolio Management System (CPMS)
60286

Study information

Scientific Title
A study of in-ear electroencephalography signals additionally recorded in hospitalised patients already undergoing standard clinical electroencephalography

Study objectives
The primary objective of this pilot/feasibility study is to explore whether the electroencephalography (EEG) signals recorded from within the ear canals of hospitalised patients provide clinically useful information compared to standard clinical EEG.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 02/11/2023, North West - Greater Manchester South Research Ethics Committee (Health Research Authority, Redman Place, Stratford, E20 1JQ, United Kingdom; +44 (0)207 104 8014; gmsouth.rec@hra.nhs.uk), ref: 23/NW/0313

Primary study design
Observational

Study design
Observational pilot/feasibility study

Study type(s)
Safety

Health condition(s) or problem(s) studied
Patients undergoing inpatient EEG in a hospital

Interventions
Current interventions as of 12/12/2024:
In hospitalised patients for whom standard clinical EEG is already being performed, i.e., as part of their routine care, the researchers will additionally record EEG from the ear canals using ‘ear plug’ like electrodes.

Previous interventions:
In 30 hospitalised patients for whom standard clinical EEG is already being performed, i.e., as part of their routine care, the researchers will additionally record EEG from the ear canals using ‘ear plug’ like electrodes.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
In-ear EEG electrodes

Primary outcome(s)
Recruitment rate recorded as the number of eligible participants who consent to participate in the study by 3 months

Key secondary outcome(s)
This is a pilot/feasibility study. The study is partly motivated to determine the best outcome measures for this kind of work. One outcome measure will be the Cohen’s kappa, a measure of agreement between a clinical physiologist rating of normal/abnormality of the EEG (factoring out agreement due to chance), determined from (1) the in-ear EEG signal and (2) the standard clinical EEG, in the same patients (measured at a single visit).

Completion date
30/06/2025

Eligibility

Key inclusion criteria
1. Aged ≥18 years old
2. Undergoing an in-patient clinical EEG as part of routine care
3. In any patients who lack the capacity to consent: the involvement of the patient's consultee

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Suspected or proven base of skull fracture, or any other contraindication to insertion of material into either ear canal e.g. ear infection
2. Lacking the capacity to consent and no available consultee

Date of first enrolment
08/01/2024

Date of final enrolment
30/04/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Charing Cross Hospital
Fulham Palace Road
London
United Kingdom
W6 8RF

Study participating centre
National Hospital for Neurology and Neurosurgery, Chalfont
Chalfont Centre
Chalfont St. Peter
Gerrards Cross
United Kingdom
SL9 0RJ

Sponsor information

Organisation
Imperial College London

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

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

IPD sharing plan summary
Data sharing statement to be made available at a later date