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Pilot study to test a new radio-frequency and radar device for stroke detection

Submission date
08/02/2023

Recruitment status
Recruiting

Registration date
19/04/2023

Overall study status
Ongoing

Last Edited
15/01/2025

Condition category
Nervous System Diseases

[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
Stroke is a major cause of death and disability worldwide. Treatments are time critical. The sooner they are given, the better the outcome for patients. Stroke is often suspected in the ambulance, but up to 40% of these patients turn out to have something else. It is also currently not possible to distinguish between a stroke caused by a blocked artery or one caused by bleeding into the brain. This is important as the treatments are very different. Furthermore, some treatments can only be given in specialised hospitals and it is not possible to know if patients need these treatments until they have a brain scan in hospital. If we could confirm a stroke and tell the type of stroke it was in the ambulance, patients could go to the right hospital first time and treatment could even be started in the ambulance. This will lead to better outcomes in the future for most patients.
This proposal takes advantage of recent work on methods called radio-frequency induction and microwave spectroscopy. We will combine both methods in a single portable device. Our hope is that these techniques will tell us about the changes taking place inside the skull in patients shortly after a stroke. If they do, a portable device for use in ambulances could be developed and further tested, to see if it can improve the speed and access to stroke treatments.
We will test a prototype device to see whether it can distinguish changes in the brain after stroke, comparing heathy volunteers with stroke patients.

Who can participate?
We will test the device with 20 healthy adult volunteers and 40 stroke patients within 3 days of their stroke onset.

What does the study involve?
Healthy volunteers will have up to 8 repeated measurements collected from the ABRIMS device, each taking 5 minutes. The total assessment will take no more than 2 hours and this will complete their participation in the study.
Stroke patients will undergo assessments on three occasions. The first will be just after consent and will be to collect baseline information only. The second will be 1-5 days after the stroke and will include one set of brain measurements with the ABRIMS device followed by a standard MRI

research brain scan. The third and final assessment will be either one day after their research scan, or at discharge from hospital, whichever is sooner. This will be to check for any changes in health and will complete patient participation in the study.

What are the possible benefits and risks of participating?
There are no expected direct benefits to participants, but we hope that the study will lead to improvements to care for stroke patients in the future. There are no increased risks to taking part in this research project. The ABRIMS device uses radio waves and radar to take readings from the brain. The strength of these waves is much less than existing medical devices and mobile phones and no adverse effects are expected.

Where is the study run from?
The research is organised by the Research Team at Northern Care Alliance NHS Foundation Trust in partnership with the University of Manchester and management oversight (Sponsorship) is provided by Northern Care Alliance NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
October 2022 to March 2026

Who is funding the study?
Engineering and Physical Sciences Research Council (EPSRC) (UK)

Who is the main contact?
Dr Adrian Parry-Jones, adrian.parry-jones@manchester.ac.uk

Contact information

Type(s)
Principal Investigator

Contact name
Dr Adrian Parry-Jones

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
324472

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 324472

Study information

Scientific Title
Assessment of Brain-injury using Radio-Frequency Induction and Microwave Spectroscopy

Acronym
ABRIMS

Study objectives
Magnetic Detection Electrical Impedance Spectroscopy (MDEIS) and Microwave Radar (MWR), either individually or in combination, may demonstrate asymmetry consistent with the side of the lesion in the presence of stroke of either ischaemic or haemorrhagic type.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 13/10/2023, North West - Greater Manchester South Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8014; gmsouth.rec@hra.nhs.uk), ref: 23/NW/0221

Study design
Single-centre pilot evaluation

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
See trial outputs table

Health condition(s) or problem(s) studied
Stroke

Interventions
Current interventions as of 15/01/2025:
We will conduct a pilot evaluation of a novel Magnetic Detection Electrical Impedance Spectroscopy (MDEIS) and Microwave Radar (MWR) device to determine its potential as a diagnostic tool for stroke. We will first test the device on up to 40 healthy volunteers to determine repeatability and refine our procedures. Following this up to 40 acute stroke patients admitted to Salford Royal Hospital will be invited to participate in a cohort study. Participants will undergo measurements with the novel ABRIMS device immediately prior to a research MRI brain scan. Monitoring for adverse events will be performed during measurements and after 24 hours, which completes participation in the study.

Previous interventions:
We will conduct a pilot evaluation of a novel Magnetic Detection Electrical Impedance Spectroscopy (MDEIS) and Microwave Radar (MWR) device to determine its potential as a diagnostic tool for stroke. We will first test the device on up to 20 healthy volunteers to determine repeatability and refine our procedures. Following this up to 40 acute stroke patients admitted to Salford Royal Hospital will be invited to participate in a cohort study. Participants will undergo measurements with the novel ABRIMS device immediately prior to a research MRI brain scan. Monitoring for adverse events will be performed during measurements and after 24 hours, which completes participation in the study.

Intervention Type
Device

Phase
Phase II

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

Primary outcome measure
Asymmetry index, determined from the microwave and MDEIS device, measured at a single timepoint in healthy volunteers and at 1 to 5 days after symptom onset in stroke patients

Secondary outcome measures
Transimpedance (Z), determined from the MDEIS device, measured at a single time point in healthy volunteers and at 1 to 5 days after symptom onset in stroke patients

Overall study start date
01/10/2022

Completion date
30/03/2026

Eligibility

Key inclusion criteria
Stage A: Healthy volunteers:
1. Aged 18 years or over
2. No significant health problems deemed by the investigator as likely to interfere with the study

procedures or data analysis (e.g. previous or existing cerebral pathology)
3. Able to provide informed consent

Stage B: Stroke patients:
1. Aged 18 years or over
2. Diagnosis of supratentorial ischaemic stroke or spontaneous intracerebral haemorrhage, within 72 h of symptom onset
3. Research MR scan can be performed within 5 days of admission
4. Likely to be able to safely complete study procedures, in the opinion of the lead clinical investigator or delegated clinical investigator

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

Key exclusion criteria
Stage A: Healthy volunteers:
Any intracranial or extracranial metallic implant

Stage B: Stroke patients:
1. Any intracranial metallic implant
2. Any extracranial metallic implant
3. Any contraindication to magnetic resonance scanning
4. Pre-existing intracranial pathology likely to interfere with measurements (e.g. previous stroke, tumour)
5. Any known condition which, in the opinion of the researcher, is likely to interfere with the planned recordings
6. Patient has undergone a neurosurgical procedure during the current admission, or this is planned within the next 24 h
7. Female patient who may be pregnant or is breastfeeding
8. Known allergy to electrodes
9. Any other significant disease or disorder which, in the opinion of the PI or his delegate, may put the participant at risk because of participation in the study, or may influence the result of the study, or the participant’s ability to participate in the study

Date of first enrolment
01/01/2024

Date of final enrolment
30/09/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Salford Royal Hospital
Stott Lane
Eccles
Salford
United Kingdom
M6 8HD

Sponsor information

Organisation
Northern Care Alliance NHS Foundation Trust

Sponsor details
Salford Royal Hospital
Stott Lane
Salford
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United Kingdom
M6 8HD
+44 1617897373
RDresearch@nca.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.ncaresearch.org.uk/

Funder(s)

Funder type
Government

Funder Name

Engineering and Physical Sciences Research Council

Alternative Name(s)
UKRI Engineering and Physical Sciences Research Council, Engineering and Physical Sciences Research Council - UKRI, Engineering & Physical Sciences Research Council, EPSRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The results of the project would be disseminated through publication, using open access where possible, and presentation by the investigators at conferences. Successful conclusion of the project should result in intellectual property and we would investigate the commercial potential in collaboration with local partners. The study and results will also be publicised more widely via the Northern Care Alliance R&I website.

Intention to publish date
30/03/2026

Individual participant data (IPD) sharing plan
Individual patient data will be shared with academic researchers upon reasonable request to Dr Adrian Parry-Jones (adrian.parry-jones@manchester.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 0.2		17/04/2023	No	Yes