







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

Submission date 08/02/2023	Recruitment status No longer recruiting	 Prospectively registered
		 Protocol not yet added
Registration date 19/04/2023	Overall study status Completed	 SAP not yet added
		 Results not yet added and study completed for less than 1 year
Last Edited 10/07/2023	Condition category Nervous System Diseases	 Raw data not yet added
		 Study completed

Plain English Summary

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 healthy 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 July 2024

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

ORCID ID

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

324472

ClinicalTrials.gov number

Nil known

Protocol/serial number

IRAS 324472

Study information

Scientific Title

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

Acronym

ABRIMS

Study hypothesis

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

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

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

Condition

Stroke

Interventions

We will conduct a pilot evaluation of a novel Magnetic Detection Electrical Impedance Spectroscopy (MDEIS) and Microwave Radar (MWR) device to determine potential as a diagnostic tool in stroke. We will first test the device in 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 complete 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

Overall study end date

01/07/2024

Eligibility

Participant 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

60

Participant 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

Recruitment start date

01/09/2023

Recruitment end date

30/06/2024

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
England
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, 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

31/12/2024

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