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Evaluation of a new portable test to identify patients with complex stroke

Submission date 06/08/2018	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 11/09/2018	**Overall study status** Completed	
Last Edited 13/12/2021	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Making a diagnosis of stroke can be difficult. Some people suffer symptoms which suggest a stroke but assessments and tests at hospital confirm a different diagnosis such a migraine or infection. When a stroke does occur, faster treatments for some types of stroke can improve the chances of making a full recovery. However, some stroke treatments are only available in very specialised regional hospitals. Currently there are no specific tests that can be used in emergency ambulances to help make a diagnosis of stroke or to determine the type of stroke. Consequently, some patients have to be transferred to a second hospital after initial assessments and tests have been conducted at a first hospital. The aim of this study is to evaluate a simple new test which may help to make a diagnosis of certain types of stroke. The test is a non-invasive device which is worn on the head like a pair of spectacles. Taking just 3 minutes, the test measures differences in fluid levels in the brain which change in stroke. Readings produced by the device may be able to distinguish certain types of stroke.

Who can participate?
Patients aged 18 or over with symptoms which suggest a stroke, immediately after their arrival at hospital

What does the study involve?
Patients undergo the new test and all routine tests which would be conducted to investigate a possible stroke. The results of the new test are compared with routine tests to determine if this new test is useful.

What are the possible benefits and risks of participating?
If the results of this study are encouraging, further research will be carried out using the test in emergency ambulances. There are no direct benefits to individuals who take part in the study, but it is hoped that care for future patients will be improved as a result of this research. There should be few risks to taking part as the test is non-invasive and should not cause pain or discomfort.

Where is the study run from?
Newcastle Upon Tyne Hospitals Trust (UK)

When is the study starting and how long is it expected to run for?
January 2018 to July 2021

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Dr Lisa Shaw
lisa.shaw@ncl.ac.uk
(updated 13/11/2020, previously: Dr Louise Sutcliffe
louise.sutcliffe@ncl.ac.uk)

Contact information

Type(s)
Scientific

Contact name
Dr Lisa Shaw

Contact details
Population Health Sciences Institute
Faculty of Medical Sciences
Henry Wellcome Building
Newcastle University
Newcastle upon Tyne
United Kingdom
NE2 4HH
+44 (0)191 208 3826
lisa.shaw@ncl.ac.uk

Additional identifiers

Protocol serial number
38969

Study information

Scientific Title
Asymmetrical Bioimpedance in the Anterior Circulation for Urgent Stratification of Stroke (ABACUS Stroke): a diagnostic accuracy study

Acronym
ABACUS Stroke

Study objectives
The study aims to determine if Cerebral Bioimpedance (CBA) measurement using the Cerebrotech Visor System device can identify certain types of stroke.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Newcastle & North Tyneside 1 Research Ethics Committee, 24/08/2018, ref: 18/NE/0219

Primary study design
Observational

Study design
Observational; Design type: Cohort study

Study type(s)
Diagnostic

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

Interventions
This research study is evaluating a new test which may help diagnose certain types of stroke. The new test is a non invasive device (called 'Cerebrotech Visor System') which measures changes in brain fluid levels to give a 'cerebral bioimpedence asymmetry' (CBA) reading. These readings may be able to diagnose certain types of stroke.

Patients arriving at hospital with a paramedic diagnosis of suspected stroke which commenced within 4 hours are suitable for inclusion provided that there are no contraindications to performing the CBA measurement (e.g. agitation which would make it difficult to wear the Visor). The CBA measurement needs to be performed very soon after arrival at hospital and staff involved in urgent assessment of suspected stroke patients will be trained about this research project and in the use of the Visor such that eligible patients can be included.

The Visor device is worn like a pair of spectacles over the forehead. It is non invasive and should not cause any discomfort. The measurement process takes about 3 minutes and can be performed alongside other routine assessments. Measurement uses low power electromagnetic waves to measures alterations in electrical properties of brain tissue which result from changes in fluids. The power density is very low, and there are no known complications following exposure to low-energy electromagnetic fields.

Study trained staff will give a verbal explanation of the CBA measurement process before the test is performed. A formal research consent process will not be conducted before the test as suspected stroke patients need urgent assessment and treatment and a formal research process at this time would result in unacceptable delays to care.

Once the urgent assessments and treatments are completed, all patients who have undergone a CBA measurement will be approached about study enrolment. A number of consent processes will be used to offer participation to all patients suitable for the Visor test. A standard information sheet and consent form will be used with patients with mental capacity. For patients with communication difficulties after stroke (aphasia) a set of 'easy access' documentation has been designed. For patients without mental capacity either a personal or professional consultee

will be required. For patients who die before consent can be obtained, a declaration by the study investigator will be required and where patients have been discharged before consent can be obtained a postal consent process will be used.

Once consent is obtained, routine clinical data required for the study analyses will be collected. There is no study specific data collection. Most data will be transcribed from medical records onto the research data collection forms/online research database. As all imaging data (e.g CT scans) will be reported by a blinded neuro-radiologist, copies of the images are required by the research team. These will be labelled by the participants study number only and provided to the study team on CD.

Should consent not be obtained for any reason, CBA measurement data will be deleted and no further study specific processes will be conducted.

Intervention Type
Other

Primary outcome(s)
1. The diagnostic accuracy of CBA measurement performed using the Cerebrotech Visor System to identify complex stroke in patients arriving at hospital with a paramedic assigned diagnosis of suspected stroke. Complex stroke is defined as ischaemic stroke caused by large vessel occlusion (LVO), or symptomatic severe anterior vessel stenosis, or haemorrhagic stroke ≥60 ml in volume, or previous territorial stroke.
2. The diagnostic accuracy of CBA measurement performed using the Cerebrotech Visor System to identify only ischaemic stroke caused by LVO in patients arriving at hospital with a paramedic assigned diagnosis of suspected acute stroke.

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
31/07/2021

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Transportation to the study hospital by ambulance
3. New stroke suspected by ambulance personnel before hospital arrival
4. At least responsive to tactile stimuli (i.e. A, V or P on the AVPU scale) on hospital arrival
5. Within 6 hours of last known well time or symptom onset time (hospital specialist judgement)
6. Brain imaging is intended to be or has been conducted within 60 minutes of hospital arrival
7. A CBA reading can be attempted +/- 30 minutes of the first brain imaging
8. The CBA reading will be within 6 hours of a hospital stroke specialist last known well time or symptom onset time

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Already assessed at another hospital and transfer to the regional neurosciences centre is for further investigation or treatment
2. Hypoglycaemia (capillary glucose < 3.5 mmol/l)
3. Presence of any known implanted electro-stimulating devices in the head and neck
4. Presence of any known metallic craniofacial implants, such as bone fixation plates or cranioplasty (aneurysm coils or clips, are acceptable)
5. Recent craniotomy or other reason known for the presence of intra-cranial air
6. Physical inability to wear the investigational device (e.g. skin lesions on scalp, haematomas)
7. Any other condition, which in the judgment of the stroke clinician might prevent the patient from tolerating CBA measurement or brain imaging (e.g. severe agitation or requiring immediate ITU admission)

Date of first enrolment
01/10/2019

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Newcastle Upon Tyne Hospitals Trust
Royal Victoria Infirmary
Queen Victoria Rd
Newcastle upon Tyne
United Kingdom
NE1 4LP

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	20/02/2020	02/03/2020	Yes	No
HRA research summary			26/07/2023	No	No