ISRCTN18134070 https://doi.org/10.1186/ISRCTN18134070

A study to demonstrate the ability of the EMTensor brain-imaging scanner to identify and distinguish different acute brain damage in patients with brain disorders

Submission date
04/02/2019

Recruitment status
Stopped

Registration date
14/03/2019

Overall study status
Stopped

Last Edited
05/11/2019

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and Study Aims:
Each year about 15 million people suffer from stroke worldwide. Half of them are left permanently disabled or worse. There are two main types of strokes: ischemic and hemorrhagic strokes. The majority of all strokes is of ischemic origin caused by a blood clot blocking a vessel in the brain and thereby reducing or blocking the blood flow and oxygen supply in parts of the brain causing damage in the tissue.
Less frequently, strokes are caused by severe bleeding from a ruptured vessel resulting in damage by increasing the pressure in the head called haemorrhagic stroke. Therapy of a stroke due to a blood clot would be contrary to treatment of bleeding.
Today different imaging procedures are available. These include Magnetic Resonance Imaging (MRI), Computed Tomography (CT) or Positron Emission Tomography (PET-) Scan, which are either using radiation and/or contrast agents.
The medical device in this study uses a completely different technology for diagnosis of stroke that we all know from our daily life. The device is called the EMTensor-Brain-Scanner because it is using electro-magnetic fields. We are surrounded by electromagnetic fields every day. These are generated, among others, by our microwave ovens or by our cellphones. Electromagnetic “radiation” from the EMTensor-Brain-Scanner is much weaker than the electromagnetic field created by our phones. Besides, the device does not use ionizing radiation like x-rays and the scanner needs no contrast agents for imaging. It is small, lightweight and can be easily brought to the patient’s bedside.
The EMTensor-Brain-Scanner is designed to assist doctors quickly diagnose patients with stroke symptoms and to help them distinguish between a stroke due to a blood clot from a stroke due to bleeding in order to speed up the decision for treatment and its initiation. It can also provide images of other potential disorders in the head like tumours.

Who can participate?
Only patients admitted to the above-named hospital in Stoke-on-Tent with acute neurological complications, for example, a recent stroke either caused by blood clots or bleeding or with

brain tumours can participate in the study. They have to be 18 years or older. Participants can be of any gender, though pregnant or lactating women will not be allowed to participate in the study.

What does the study involve?
The participation in this study involves the following procedures:
Patients that present with one of the above-named conditions in the hospital will receive the standard care first. If they meet the inclusion criteria and none of the exclusion criteria they will be given the choice to participate in the study.
After they signed informed consent, their medical history will be recorded and a standard physical examination of their vital signs (blood pressure, heart rate) will be done. Female participants of childbearing potential will be asked to provide a urine sample for a pregnancy-test (pregnant women will be excluded from this study).
Afterwards, the patients will receive one EMT-scan. They will be wearing a cap filled with some soft cream or gel that could be a bit chilly.
They will be settled in their bed and the device will be placed around their heads. The examination with the scanner will take only a couple of minutes.
Within 48 hours after the examination with the EMT-scanner they will be questioned by someone from the research team about any discomfort they might have experienced during the examination and afterwards. They can also report any discomfort at any time to someone from the hospital care team if they feel the need.

What are the possible benefits and risks of participating?
There will be no direct benefits from participating in this study. The imaging device used in this study uses a new technology. Participation will add new and additional information for the sponsor to optimize the use of the device and its technology. Thus, future stroke patients and also patients with other disorders of the head/brain will benefit from this promising diagnostic procedure.
There will also be no specific risks to the participants. The technology/device uses a very low electromagnetic power field that is much weaker than the one a cellphone creates in one's pocket. The strength of the EMTensor electromagnetic field is about 250 times weaker than for example the electromagnetic field from our cell phones. Earlier clinical trials showed that some of the participants had some pressure marks on the forehead for a short time due to the design of the cap they were wearing during the examination. Other participants also reported discomfort from the coolness of the gel/cream used inside the cap.

Where is the study run from?
This study will take place in only the University hospital in Stoke-on-Tent in the United Kingdom for the moment.

When is the study starting and how long is it expected to run for?
It is planned to enrol about 40 patients into the study and to enrol the first patients at the beginning of March 2019. The last patient should participate about a year later in March 2020.

Who is funding the study?
The study is funded by the company that developed the new device. The name of the company is EMTensor GmbH. They are located in Vienna in Austria. web-site: http://www.emtensor.com

Who is the main contact?
The Principal Investigator is Professor Christine Roffe, MD FESO, email: Christine.Roffe@uhnm.nhs.uk

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Additional identifiers

Protocol serial number
Version 0.1

Study information

Scientific Title
Proof of Concept Study of the ability of the EMTensor Brain Imaging Scanner (EMT-Scanner) to identify intracranial pathologies in patients with neurological disorders

Acronym
EMTensorG3-PoC

Study objectives
Proof of Concept: To determine the appearance of different intracranial pathologies on the EMT-Scanner

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Observational

Study design
A multi-center, single-arm, open, exploratory, proof of concept study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Neurological disorders

Interventions
Patients presenting with acute stroke or other intracranial pathologies (e.g. ischemic stroke, intracerebral haemorrhage, subdural haemorrhage, subarachnoid haemorrhage, brain tumours, cerebral oedema) identified on baseline CT or MRI head scan, will receive one examination with the EMT-Scanner after receiving the standard care. The EMT-scan would ideally be performed within 1-2 hours after baseline CT/MRI-scan.

Intervention Type
Device

Primary outcome(s)
Presence of neuropathology identified by abnormal signal on the EMT-scan

Key secondary outcome(s)

1. Assessing the feasibility of the use of the EMT-scanner in imaging for stroke by expert comparison to standard care scans like MRI or CT-scan as baseline examinations.
2. The number of participants who complete the scan according to the protocol
3. The proportion of images determined to be of adequate quality for interpretation as determined by experts (Prof. Roffe and colleagues).
4. Incidence of all Serious Adverse Events recorded by questionnaire according to protocol at the latest 48 hours after the scan.

Completion date
31/03/2020

Reason abandoned (if study stopped)
Not disclosed

Eligibility

Key inclusion criteria
1. Aged 18 or above
2. Within one week of hospital admission with an acute neurological condition, with an intracranial pathology identified on the CT or MRI head scan (e.g. ischemic stroke, intracerebral hemorrhage, subdural hemorrhage, subarachnoid hemorrhage, brain tumors, cerebral edema)
3. Within 1-2 hours after baseline CT/MRI-scan.
4. Informed consent by the patient or by their legal representative

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Pregnancy (as determined by a positive urine pregnancy-test scheduled before the EMT-scan) or lactating females
2. Physically unable to comply with study procedures
3. Known hypersensitivity to latex
4. Patients with pacemakers or electronic defibrillators
5. Metal or metal-like implant located in head or neck-area - also ceramic implants and programmable shunts are excluded
6. Open wounds in the arear of the head and neck covered by the EMT-device
7. Participation in another clinical trial that would confound study results

Date of first enrolment
01/03/2019

Date of final enrolment
25/03/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Institute for Applied Clinical Studies Keele University
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Sponsor information

Organisation
EMTensor GmbH

Funder(s)

Funder type
Industry

Funder Name
EMTensor GmbH

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available