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Auto-regulation & cerebral blood flow in transient ischaemic attack (TIA) patients

Submission date 02/07/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 10/07/2015	**Overall study status** Completed	
Last Edited 09/07/2021	**Condition category** Nervous System Diseases	

Plain English summary of protocol

Background and study aims
A transient ischaemic attack (TIA or mini-stroke) is a warning sign of a possible future stroke and it is vital it is treated seriously and as early as possible. Following a TIA, one in 13 patients will have a stroke in the first year and this rises to more than a third in those who have had more TIAs. The aim of the study is to investigate whether there is a link between reduced blood flow in the brain following a TIA and the presence of the protein albumin in the urine (an indicator of cardiovascular damage).

Who can participate?
Patients aged at least 18, with a confirmed TIA and normal cognitive function

What does the study involve?
In addition to standard examination, all participants are asked to give a urine sample collected over a 24 hour period after the TIA event. This is used to place them in the appropriate patient group. A small quantity of the urine sample is kept for further protein analysis at a later date. Measurements of blood flow in the brain is taken in a quiet room in the hospital using Trans-Cranial Doppler (a non-invasive ultrasound measurement). This is then compared to changes in blood pressure measured using a blood pressure equipment. A heart trace (using ECG machine) is also used to check each participants heart rate. These tests will take a further 40-60 minutes of the patient's time.

What are the possible benefits and risks of participating?
The cost of analysing blood and urine samples will be paid by the research grant, and the results will be made available to the treating consultant for his consideration. The ultrasound (trans-cranial Doppler) results will need several days to weeks in order to be analysed, so they will not have any benefits to patients. However, any abnormal readings will be reported immediately to the treating consultant. Trans-cranial Doppler uses relatively high power ultrasound that may generate heat. However, it has been extensively used over many years on patients or healthy volunteers and no deleterious effects have been reported. Most of the energy generated by the trans-cranial Doppler is absorbed outside at the skull boundary, rather than in the brain itself. We will be using commercial CE certified medical equipment, with a thermal index below 1, in accordance with current recommendations of the British Medical Ultrasound Society.

Where is the study run from?
Salisbury District Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2015 to December 2019

Who is funding the study?
Qatar National Research Fund (QNRF), Doha, Qatar

Who is the main contact?
Professor Ahmed Khattab (scientific)

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Auto-regulation and cerebral blood flow in transient ischaemic attack (TIA) patients attending a stroke/TIA clinic: implications for stroke prevention

Study objectives

1. Cerebral autoregulation is acutely impaired in TIA patients with microalbuminuria compared to TIA patients with no microalbuminuria; this difference is time dependent
2. TIA patients with impaired cerebral autoregulation will have poorer prognostic outcomes than TIA patients with normal cerebral autoregulation

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West - Frenchay Research Ethics Committee, 02/12/2015, REC ref: 15/SW/0287

Study design
Observational single-centre cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Other

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Transient ischaemic attack (TIA)

Interventions
Transient ischaemic attack (TIA or mini-stroke) is a warning sign of a possible future stroke and it is vital that it is treated seriously and as early as possible. 1 in 13 patients will have a stroke after a TIA in the first year. Of those who have had one or more TIAs, more than a third will have a subsequent stroke. This is an observational cohort study (over two years), involving 200 patients attending a TIA Clinic. The group will be divided into two subgroups; hundred with TIA and microalbuminuria (protein in urine) and hundred with TIA but no microalbuminuria (no protein in urine). The aims are to investigate the link between impaired cerebral blood flow (CBF), measured by transcranial Doppler, and the presence or absence of microalbuminuria in both groups of patients. Patients selected will be of any age, have a confirmed TIA for the first time, no history of previous stroke, had normal cognitive functions. After the two year follow-up, the following outcomes will be examined:
1 The pattern of bilateral cerebral blood flow within the study population
2. The correlation between CBF and microalbuminuria in the subgroup of patients (those with TIA and microalbuminuria)
3. The correlation between CBF and other proteins present in the urine samples of the study population
4. Whether screening for microalbuminuria can be used as a surrogate marker for impaired

cerebral blood flow in TIA clinics in order to help in identifying a subgroup of TIA patients who are at grave risk of developing microvascular and macrovascular disease, including stroke
5. The effects of confounding factors (such as diabetes and kidney diseases) on the above outcomes and how to deal with them

Intervention Type
Other

Primary outcome measure
Cerebral blood flow and cerebral autoregulation, measured at 3hr, <24hr, and >24 hours after TIA.

Secondary outcome measures
1. First and subsequent (further) strokes (or vascular events) after TIA, over a one year period
2. Vascular death “death related to cerebro- or cardio-vascular diseases”, over a one year period

Overall study start date
01/01/2015

Completion date
31/12/2019

Eligibility

Key inclusion criteria
1. Age at least 18 years
2. Able and willing to give consent
3. Had a confirmed TIA for the first time
4. No history of previous stroke
5. Had normal cognitive functions

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Age less than 18 or more than 80 years
2. Unable to give consent
3. Had previous or more than one confirmed TIAs

4. Had a history of previous stroke
5. Had impaired cognitive functions

Date of first enrolment
01/09/2015

Date of final enrolment
01/09/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Salisbury District Hospital
Salisbury NHS Foundation Trust
Odstock Road
Salisbury, Wiltshire
United Kingdom
SP2 8BJ

Sponsor information

Organisation
Bournemouth University (UK)

Sponsor details
R&KEO Department
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United Kingdom
BH12 5BB

Sponsor type
University/education

Website
www.bournemouth.ac.uk

ROR
https://ror.org/05wwcw481

Funder(s)

Funder type
Government

Funder Name
Qatar National Research Fund (QNRF), Doha, Qatar

Results and Publications

Publication and dissemination plan
1. Presentations to the public at local, regional and national meetings
2. Presentations at national and international conferences to disseminate the findings from this project
3. Presentations at a number of professional bodies and associations fora and meetings in the UK
4. Publications in peer-reviewed clinical and scientific journals
5. Internal reports, and other publications such as chapters in books, press and media
6. Presentations to relevant groups (education groups, service users groups, relevant community groups, clinicians, nurses, carers)
7. Writing research blogs on Bournemouth University website, with contribution from all researchers involved in this project
8. Short articles and eye-catching titles on the Websites of (Bournemouth University, Salisbury District Hospital, etc) with links to peer-reviewed articles, and to major findings of the project and research staff involved in this project

Intention to publish date
31/12/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as this was not stated in the submission for ethics approval. The anonymised data for the study (at Bournemouth) were encrypted and password protected; e-mails were encrypted and encrypted memory sticks were used for the storage and transfer of data. Bournemouth University (BU) has a very strict policy and guidelines on sending sensitive information and data to and from BU. For further information and details of the guidelines, please see https://www1.bournemouth.ac.uk/about/governance/sending-sensitive-data-bu. BU staff are also supported by an expert IT team and state-of-the-art technology at BU, with a dedicated Senior Manager in charge of the Information Security and a dedicated Assistant Director of IT Services who is responsible for the implementation of BU IT Security.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No