

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

<b>Submission date</b> 02/07/2015	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 10/07/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 09/07/2021	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## 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**  
Prof Ahmed Khattab

**ORCID ID**  
<http://orcid.org/0000-0003-2541-4544>

**Contact details**  
Centre of Postgraduate Medical Research & Education  
Faculty of Health & Social Sciences  
Bournemouth University  
Bournemouth  
United Kingdom  
BH1 3LG

## 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

Bournemouth

England

United Kingdom

BH12 5BB

**Sponsor type**

University/education

**Website**

[www.bournemouth.ac.uk](http://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?
<a href="#">HRA research summary</a>			28/06/2023	No	No