

# Rapid Primary care Initiation of Drug treatment for TIA (RAPID-TIA)

<b>Submission date</b> 25/01/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 29/01/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 03/10/2018	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

People who have a transient ischemic attack (TIA) or minor stroke are at high risk of another stroke, particularly in the first week after the event. A recent study has shown that starting secondary prevention drugs early, in a specialist clinic, significantly lowers the risk of another stroke. RAPIDTIA is a pilot study to determine the feasibility of a larger study to see whether it is better for patients to receive extra medication to prevent further stroke from the primary care doctor or wait until they have been seen by a specialist.

### Who can participate?

Approximately 170 patients with symptoms suggestive of TIA or minor stroke will be recruited from the catchment of three hospital TIA clinics (Birmingham, Cambridge and Oxford) and the emergency departments of these hospitals.

### What does the study involve?

Participants with a probable diagnosis of TIA will be entered into the whole pilot study, those with possible TIA will be entered into the diagnostic study only. Participants with a probable TIA will be randomised to receive usual treatment as recommended by current guidelines (the control group) or usual treatment plus additional medications usually initiated by a specialist. All participants will be seen by a specialist as per current practice who will record final diagnosis and adjust medication accordingly. A further follow up appointment will be scheduled after 90 days. In addition, approximately 10 patients and 10 healthcare professionals will be invited to participate in one in-depth semi-structured interview lasting up to one hour. The interview will help us to identify how trial procedures might be modified for the main trial.

### What are the possible benefits and risks of participating?

Benefits include starting secondary prevention medication on the same day instead of waiting, which may reduce the risk of another stroke. Risks include extension of haemorrhagic stroke from dual anti-platelet treatment, uncertainty about the effect of early statin treatment, and unnecessary treatment due to overdiagnosis.

### Where is the study run from?

University of Birmingham (UK)

When is the study starting and how long is it expected to run for?  
December 2008 to December 2012

Who is funding the study?  
National Institute for Health Research (NIHR) (UK)

Who is the main contact?  
Dr Kate Fletcher  
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## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
10122

## Study information

**Scientific Title**  
Rapid Primary care Initiation of Drug treatment for TIA (RAPID-TIA) a pilot randomised controlled trial

**Acronym**  
RAPID-TIA

**Study objectives**  
People who have a transient ischaemic attack (TIA) or minor stroke are at high risk of a recurrent stroke, particularly in the first week after the event.  
1. Recent data suggest very early initiation of secondary prevention drugs leads to an 80% reduction in risk of stroke recurrence.  
2. This raises the question as to whether these drugs in addition to aspirin should be given before being seen by a specialist i.e. in primary care or in the emergency department.

The aim of the RAPID-TIA pilot trial is to determine the feasibility of a randomised controlled trial and cost effectiveness analysis to ask: Should general practitioners and emergency doctors (primary care physicians [PCP]) initiate secondary preventative measures in addition to aspirin in people they see with suspected TIA or minor stroke at the time of referral to a specialist? We will recruit 170 patients from 30 general practices and 3 emergency departments and randomly assign them to usual care or usual care plus additional early initiation of secondary prevention drugs (a blood pressure lowering protocol, simvastatin 40mg and dipyridamole 200mg m/r bd). The primary outcome of the main study will be stroke at 90 days. This pilot study will be used to estimate key parameters that are needed to design the main study and to estimate accuracy of primary care diagnosis of TIA.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Cambridgeshire 3 Research Ethics Committee, 03/05/2011, ref: 11/EE/0040

### **Study design**

Randomised; Interventional; Design type: Process of Care

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Transient ischaemic attack / Stroke

### **Interventions**

Intervention plus usual care group

Intervention group patients will be treated with additional secondary prevention medications, unless there are clinical contra-indications, prior to referral to a specialist clinic. Treatment will comprise of dual antiplatelets, blood pressure lowering medication, and simvastatin 40mg. All patients will then be referred to a specialist clinic as per NICE guidelines (with the degree of urgency dictated by the ABCD2 score).

#### **Dual antiplatelets**

In patients not already on antiplatelet or anticoagulant therapy, aspirin 300mg once daily will be started for the first two weeks or until reduced by the specialist. Dipyridamole MR 200mg twice daily will be started in patients not already on antiplatelet or anticoagulation therapy other than aspirin. Anticoagulation or antiplatelet agents the patient is already taking will be continued.

#### **Blood pressure lowering medication**

Unless BP is below 130mmHg systolic on either of two readings taken one minute apart or the patient is already taking all three of a thiazide diuretic, ACE-inhibitor and calcium channel blocker, then one of these three classes of medication will be initiated according to the PCPs clinical choice. If the patient is already taking all three drug classes, one agent should be dose increased within its licensed dosage according to the PCPs clinical choice.

Simvastatin 40mg once daily

Simvastatin 40mg daily will be started unless the patient is already on statin treatment of equivalent intensity.

Clinicians should check liver function or renal function when starting statins and blood pressure lowering medications according to their usual practice, but results are not mandatory prior to initiating treatment.

### 3.8.2 Usual care group

Control group: if patients are not already on antiplatelet therapy, a loading dose of aspirin will be administered (300mg daily) and patients will be referred to a specialist clinic as per NICE guidelines (with the degree of urgency dictated by the ABCD2 score).(8)

All patients will be instructed to continue on their usual medications unless a clinician makes a specific decision to alter them for any reason.

Follow Up Length: 3 month(s)

### **Intervention Type**

Drug

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

Aspirin, Dipyridamole, simvastatin

### **Primary outcome(s)**

All stroke within 90 days of randomisation

### **Key secondary outcome(s)**

Clinical outcomes within 90 days of randomisation

All vascular events

All major bleeding

Death

Ischaemic stroke

Haemorrhagic stroke

Fatal stroke

Disabling stroke

Non-disabling stroke

TIA

We will also explore the benefit of analysing clinical outcome at different lengths of time, including 7 days from randomisation, 7 and 90 days from first symptoms, and between randomisation and first specialist appointment.

### **Completion date**

31/12/2012

## **Eligibility**

**Key inclusion criteria**

Patients over 18 years of age (male and female) presenting to a primary care physician with symptoms suggestive of TIA or minor stroke (first or recurrent, but only one event per patient in the trial)

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

Patients requiring immediate emergency admission, where symptoms have not substantially resolved by the time they see primary care physician

**Date of first enrolment**

01/11/2011

**Date of final enrolment**

31/12/2012

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

University of Birmingham

Birmingham

United Kingdom

B15 2TT

**Sponsor information**

## Organisation

University of Birmingham (UK)

## ROR

<https://ror.org/03angcq70>

## Funder(s)

### Funder type

Government

### Funder Name

National Institute for Health Research (NIHR) (UK) Grant Codes: PB\_PG\_1207\_15216

### Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not provided at time of registration

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	02/07/2013		Yes	No