

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

Submission date 25/01/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 29/01/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 03/10/2018	Condition category 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. RAPID-TIA 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

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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 measure

All stroke within 90 days of randomisation

Secondary outcome measures

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.

Overall study start date

01/11/2011

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

UK Sample Size: 170

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

England

United Kingdom

Study participating centre

University of Birmingham

Birmingham

United Kingdom

B15 2TT

Sponsor information**Organisation**

University of Birmingham (UK)

Sponsor details

Edgbaston

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Sponsor type

University/education

Website

<http://www.birmingham.ac.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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	02/07/2013		Yes	No