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

Submission date
25/01/2013

Recruitment status
No longer recruiting

Registration date
29/01/2013

Overall study status
Completed

Last Edited
03/10/2018

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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?
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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

Primary study design
Interventional

Study design
Randomised; Interventional; Design type: Process of Care

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 emegency 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?
Protocol article	protocol	02/07/2013		Yes	No