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Fast Assessment of Stroke and Transient ischemic attack to prevent Early Recurrence (FASTER) : a pilot study for a multicentre randomised controlled, double blind trial of combination anti-platelet therapy versus aspirin and statin therapy to prevent stroke in those at high-risk of early recurrence after transient ischemic attack or mild stroke

Submission date 01/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/09/2005	**Overall study status** Completed	
Last Edited 25/01/2019	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00109382

Secondary identifying numbers
MCT-63529

Study information

Scientific Title
Fast assessment of stroke and transient ischaemic attack to prevent early recurrence (FASTER): a randomised controlled pilot trial

Acronym
FASTER

Study objectives
1. To determine whether a rapid commencement of clopidogrel plus aspirin (ASA) within 12 hours of acute transient ischemic attack (TIA) or minor stroke is more effective than ASA in reducing the 90-day risk of stroke by an absolute difference of 2%
2. To determine whether a rapid commencement of simvastatin plus ASA within 12 hours of acute TIA or minor stroke is more effective than ASA in reducing the 90-day risk of stroke by an absolute difference of 2%
3. To determine whether a rapid commencement of clopidogrel plus simvastatin plus ASA within 12 hours of acute TIA or minor stroke is more effective than ASA in reducing the 90-day risk of stroke by an absolute difference of 4%
4. To determine whether the incidence of adverse events is different among treatment groups

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Health Research Ethics Board of University of Calgary on the 4th October 2004.

Study design
Multicentre randomised controlled double blind trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Stroke

Interventions
All patients will receive open-label enteric-coated aspirin in the range of 81 mg, with dose determined by the treating physician.
Arm 1: Clopidogrel 300 mg + simvastatin 40 mg on day 1, then clopidogrel 75 mg once daily (OD) + simvastatin 40 mg OD on days 2 - 90
Arm 2: 4 Clopidogrel-placebo tablets + simvastatin 40 mg on day 1, then clopidogrel-placebo tablet OD + simvastatin 40 mg OD on days 2 - 90
Arm 3: Clopidogrel 300 mg + 1 simvastatin-placebo tablet on day 1, then clopidogrel 75 mg OD + 1 simvastatin-placebo tablet OD on days 2 - 90
Arm 4: 4 Clopidogrel-placebo tablets + 1 simvastatin-placebo tablet on day 1, then 1 clopidogrel-placebo tablet OD + 1 simvastatin-placebo tablet OD on days 2 - 90

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Clopidogrel, simvastatin, aspirin

Primary outcome measure
Any stroke within three months.

Secondary outcome measures
Composite of any stroke, myocardial infarction and vascular death.

Overall study start date
01/04/2003

Completion date
30/03/2004

Eligibility

Key inclusion criteria
1. Patients with TIA or minor acute ischemic stroke (National Institutes of Health Stroke Scale [NIHSS] equalling 3 at the time of randomisation) who must not be candidates for acute thrombolytic or anticoagulant therapy within 12 hours of symptom onset
2. Aged 40 years or over, either sex
3. Patients with:
3.1. Weakness at time of TIA/minor stroke and/or language disturbance at time of TIA/minor

stroke
3.2. Duration of neurological deficit (TIA) equals 5 minutes
4. Patients can be randomised within 12 hours of symptom onset. Symptom onset is defined by the 'last seen well' principle

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
500

Key exclusion criteria
1. Patients with pure sensory symptoms, pure vertigo or dizziness, or pure visual loss
2. Patients for whom thrombolysis or other acute intervention is indicated as the current standard of care
3. Patients who are currently on statin therapy, antiplatelet therapy (not including aspirin), or long-term Non-Steroidal Anti-Inflammatory Drugs (NSAIDs, but not COX inhibitors), or anticoagulation
4. Patients, who in the opinion of the site Investigator, should be commenced on statin therapy
5. Patients with neurological deficit due to intracranial hemorrhage (intracerebral hemorrhage, subarachnoid hemorrhage, subdural hematoma, epidural hematoma), tumor, infection or any finding not consistent with acute brain ischemia as the cause of presenting symptoms
6. Presumed cardiac source of embolus (e.g. atrial fibrillation, prosthetic cardiac valve, known /suspected endocarditis)
7. Patient with a concomitant acute coronary syndrome (acute myocardial infarction or unstable angina)
8. Modified Rankin Score of 3 or more (pre-morbid historical assessment)
9. Patients in whom the qualifying event was due to a complication of cerebral angiography, a revascularization procedure or trauma
10. Uncontrolled hypertension at baseline (systolic blood pressure greater than 180 mmHg or diastolic blood pressure greater than 110 mmHg), or malignant hypertension defined by brain plus other acute organ involvement due to acute hypertension
11. Women who are breast-feeding or pregnant. Women of childbearing potential must have a negative pregnancy test prior to randomization. Women of childbearing potential may still participate in the trial but must plan on not becoming pregnant during the course of the study and must practice a suitable method of birth control. If a patient becomes pregnant or begins breast-feeding during the study, both study drugs will be discontinued immediately, and the patient followed for the duration of the study
12. Evidence of contraindication for use of Trial Medication:
12.1. Current or past history of severe renal insufficiency
12.2. Current or past history of severe hepatic dysfunction
12.3. Current or past history of thrombocytopenia
12.4. Current or past history of neutropenia
12.5. Current or past history of bleeding diathesis or coagulopathy
12.6. Current or past history of serious systemic bleeding

12.7. Past History of hypersensitivity to aspirin, thienopyridine drugs (clopidogrel or ticlopidine) or statins
13. Life expectancy of less than 90 days
14. Geographical or other factors that render follow-up impractical or that render evaluation of outcome events impossible (e.g. severe dementia). Patients may be randomised who could and are willing to complete their follow-up at another participating centre
15. Participation in another clinical therapeutic trial (drug or device) either concurrently or within the previous 30 days, or prior participation in FASTER

Date of first enrolment
01/04/2003

Date of final enrolment
30/03/2004

Locations

Countries of recruitment
Canada

United Kingdom

Study participating centre
Room 1162
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Sponsor information

Organisation
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Sponsor type
University/education

Website
http://www.ucalgary.ca/

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-63529)

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?
Results article	results	01/11/2007	25/01/2019	Yes	No