ISRCTN73630073 https://doi.org/10.1186/ISRCTN73630073

Platelet oriented inhibition in new transient ischaemic attack (TIA) and minor ischemic stroke

Submission date	Recruitment status	[_] Prospectively registered
25/02/2014	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/02/2014	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/01/2020	Circulatory System	

Plain English summary of protocol

Background and study aims
A transient ischaemic attack (TIA), often referred to as a “mini stroke” is a condition caused by a temporary disruption of blood flow to the brain. This causes stroke-like symptoms, such as difficulty talking or numbness/weakness in the face, arms or legs. In the case of a TIA, these symptoms pass quickly, however when they last for more than 24 hours, it becomes a minor ischaemic stroke (MIS), so called because only minimal damage is caused. When a person has had a TIA or MIS, they have a greater risk of developing serious complications arising from blocked blood vessels (major ischemic vascular events), such as a major stroke or heart attack. In order to prevent this, patients are often prescribed antiplatelet medications, which are used to reduce the risk of blood clots forming. Aspirin is one of the most commonly used antiplatelet medications, although there are a range of other drugs available, such as clopidrogrel. The aim of this study is to find out whether treatment with clopidrogrel and aspirin is more effective at preventing future major ischemic vascular events in TIA and MIS patients than aspirin alone.

Who can participate?
Adults who have had a high-risk TIA or minor ischaemic stroke.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group take clopidogrel and aspirin for 90 days. After an initial dose of 600mg clopidogrel (so that patients can start getting an effect from the drug), patients take 75mg clopidogrel every day, as well as 50-325mg aspirin per day. Those in the second group receive dummy pills (placebo) of identical in shape and size to the clopidogrel in the same treatment regimen, as well as 50-325mg aspirin per day. Participants in both groups are followed up after 90 days in order to find out how many have gone on to have a stroke or heart attack (major ischemic vascular events).

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Acute Vascular Imaging Centre, John Radcliffe Hospital (UK)

When is the study starting and how long is it expected to run for?
January 2014 to June 2016

Who is funding the study?
National Institute of Neurological Disorders and Stroke (USA)

Who is the main contact?
Dr James Kennedy
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Study website
http://www.pointtrial.org/

Contact information

Type(s)
Scientific

Contact name
Dr James Kennedy

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00991029

Secondary identifying numbers
15499

Study information

Scientific Title
POINT: Platelet Oriented Inhibition in New TIA and Minor Ischemic stroke

Acronym

POINT

Study objectives
The purpose of this study is to determine the safety and effectiveness of the combination of low dose aspirin and a medication called clopidogrel (also known by the brand name Plavix®) in reducing the risk of stroke, heart attacks and other complications in patients recovering from stroke. The POINT trial has been designed to find out whether the combination of aspirin and clopidogrel reduces the risk of stroke, heart attacks and other complications compared to aspirin alone in patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
13/SC/0470

Study design
Randomised; Interventional; Design type: Treatment

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
Topic: Stroke Research Network, Injuries and Emergencies; Subtopic: Acute Care, Injuries and Emergencies (all Subtopics); Disease: In hospital study, Injuries and Emergencies

Interventions
Clopidogrel/aspirin group compared to a placebo/aspirin group.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
1. Aspirin 2. Clopidogrel

Primary outcome measure

Prevention of major ischemic vascular events at 90 days; Timepoint(s): The primary outcome of the trial is to determine whether clopidogrel 75mg/day by mouth after a load

Secondary outcome measures
Not provided at time of registration

Overall study start date
31/01/2014

Completion date
30/06/2016

Eligibility

Key inclusion criteria
Neurologic deficit (based on history or examination) attributed to focal brain ischemia and EITHER:
1. High risk TIA: Complete resolution of the deficit at the time of randomization AND ABCD2 score >4
Or
Minor ischemic stroke: residual deficit with NIHSS <3 at the time of randomization
2. Ability to randomize within 12 hours of time last known free of new ischemic symptoms.
3. Head CT or MRI ruling out hemorrhage or other pathology, such as vascular malformation, tumor, or abscess, that could explain symptoms or contraindicate therapy.
4. Ability to tolerate aspirin at a dose of 50-325 mg/day.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 4150; UK Sample Size: 378

Total final enrolment
4881

Key exclusion criteria
1. Age <18 years.
2. TIA symptoms limited to isolated numbness, isolated visual changes, or isolated dizziness /vertigo.
3. In the judgement of the treating physician, a candidate for thrombolysis, endarterectomy or endovascular intervention, unless the subject declines both endarterectomy and endovascular intervention at the time of evaluation for eligibility.
4. Receipt of any intravenous or intraarterial thrombolysis within 1 week prior to index event.
5. Gastrointestinal bleed or major surgery within 3 months prior to index event.

6. History of nontraumatic intracranial hemorrhage.
7. Clear indication for anticoagulation (e.g., warfarin, heparin) anticipated during the study period (atrial fibrillation, mechanical heart valve, deep venous thrombosis, pulmonary embolism, antiphospholipid antibody syndrome, hypercoagulable state).
8. Qualifying ischemic event induced by angiography or surgery.
9. Severe noncardiovascular comorbidity with life expectancy <3 months.
10. Contraindication to clopidogrel or aspirin:
10.1. Known allergy
10.2. Severe renal (serum creatinine >2 mg/dL) or hepatic insufficiency (prior or concurrent diagnosis, with INR>1.5, or any
resultant complication, such as variceal bleeding, encephalopathy, or icterus)
10.3. Haemostatic disorder or systemic bleeding in the past 3 months
10.4. Current thrombocytopenia (platelet count <100 x109/l) or neutropenia/granulocytopenia (<1 x109/l)
10.5. History of drug induced haematologic or hepatic abnormalities
11. Anticipated requirement for long term (>7 day) nonstudy antiplatelet drugs (e.g., dipyridamole, clopidogrel,
iclopidine), or NSAIDs affecting platelet function (such as prior vascular stent or arthritis).
12. Not willing or able to discontinue prohibited concomitant medications.
13. Inability to swallow medications.
14. At risk for pregnancy: premenopausal or post menopausal woman within 12 months of last menses without a negative pregnancy test or not committing to adequate birth control (e.g., oral contraceptive, two methods of barrier birth control, or abstinence).
15. Unavailability for followup.
16. Signed and dated informed consent not obtained from patient.
17. Other neurological conditions that would complicate assessment of outcomes during follow up.
18. Ongoing treatment in another study of an investigational therapy, or treatment in such a study within the last 7 days.
19. Previously enrolled in the POINT study.

Date of first enrolment
31/01/2014

Date of final enrolment
30/06/2016

Locations

Countries of recruitment
England

United Kingdom

United States of America

Study participating centre
John Radcliffe Hospital
Acute Vascular Imaging Centre

Headley Way
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
University of California, San Francisco

Sponsor details
Neurovascular Disease and Stroke Center
400 Parnassus Ave , Eighth Floor
San Francisco
United States of America
94143

Sponsor type
University/education

Website
https://www.ucsf.edu/

ROR
https://ror.org/043mz5j54

Funder(s)

Funder type
Government

Funder Name
National Institute of Neurological Disorders and Stroke

Alternative Name(s)
National Institute of Neurological Disorders & Stroke, NIH/National Institute of Neurological Disorders and Stroke, NIH National Institute of Neurological Disorders and Stroke, Instituto Nacional de Trastornos Neurológicos y Accidentes Cerebrovasculares, The National Institute of Neurological Disorders and Stroke, National Institute of Neurological Disorders and Blindness, National Institute of Neurological and Communicative Disorders and Stroke, NINDS, NINDB, NINCDS

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

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	01/08/2013	24/01/2020	Yes	No
Results article	results	19/07/2018	24/01/2020	Yes	No
HRA research summary			28/06/2023	No	No