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Norfolk Platelet And Stroke Study (PASS)

Submission date	Recruitment status	[_] Prospectively registered
11/02/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/07/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/03/2017	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Kris Bowles

Contact details
Colney Lane
Colney
Norwich
United Kingdom
NR4 7UY
-
KRISTIAN.BOWLES@nnuh.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
9199

Study information

Scientific Title

Investigation of the clinical utility of platelet function testing following stroke and transient ischaemic attack: a non-randomised observational clinical laboratory study

Acronym
PASS

Study objectives
Platelet aggregation or stickiness is a fundamental part of having a stroke or transient ischaemic attack (TIA). Most patients following a stroke take anti-platelet drugs (e.g. aspirin) to specifically deal with this aspect of the illness, and aspirin and drugs like it have provided significant clinical benefit in terms of reducing further strokes for this patient group. Despite this anti-platelet drug treatment a number of patients go on to have further strokes (and heart attacks). We and others believe that resistance to the drugs accounts for a significant number of aspirin or anti-platelet drug failure and this may affect between 5-35% of patients. As yet we have no routinely clinically useful way of effectively and reliably assessing the effect of the antiplatelet drugs in stroke patients.

Our principal objective is to investigate the clinical utility of platelet function analysis in predicting outcomes following stroke and transient ischaemic attacks (TIA). We will be using a new generation of platelet function analysers about the size of a home computer which if found to be useful could be used in any hospital or clinic.

The study requires from the patient a blood test (one 4 ml blood tube per test on one or two occasions) where possible at the time of normal blood testing. As this automated technology for platelet function testing is new it first needs to be evaluated in our hands as follows:

1. Determine the normal reference range and imprecision of the multiplate (platelet function analyser) instrument in the NNUH laboratory in 20 healthy volunteers who do not take anti-platelet therapy and compare to published data
2. Determine the imprecision of the multiplate instrument in acute stroke patients who are receiving antiplatelet therapy
3. Establish the optimal time for testing platelet function in acute stroke patients following commencement of aspirin therapy
4. Establish the reproducibility of the multiplate test in normal

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC (ref: 09/H0310/92)

Study design
Single-centre non-randomised observational clinical laboratory study

Primary study design
Observational

Secondary study design
Non randomised controlled trial

Study setting(s)

Hospital

Study type(s)
Treatment

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

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

Interventions
1. The observations consist of a blood test to assess platelet function following stroke/TIA
2. Follow-up length: 12 months

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Platelet function result at time of stroke/TIA

Secondary outcome measures
Measured at at 90 days and 1 year:
1. Re-stroke
2. Other vascular event
3. Death

Overall study start date
01/02/2010

Completion date
31/03/2011

Eligibility

Key inclusion criteria
1. Over the age of 18 years old (we are a department that treats adult patients)
2. Patient admitted under the care of the department of medicine with a stroke/transient ischaemic attack (TIA) at the Norfolk and Norwich Hospital
3. Within 72 hours of admission with a stroke/TIA
4. Must have received one dose of at least 75 mg of aspirin orally before testing

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 80

Key exclusion criteria
1. Unfit for procedure (phlebotomy)
2. Patients not given aspirin

Date of first enrolment
01/02/2010

Date of final enrolment
31/03/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Colney Lane
Norwich
United Kingdom
NR4 7UY

Sponsor information

Organisation
Norfolk and Norwich University Hospital NHS Foundation Trust (UK)

Sponsor details
Colney Lane
Colney
Norwich

England
United Kingdom
NR4 7UY

Sponsor type
Hospital/treatment centre

Website
http://www.nnuh.nhs.uk/

ROR
https://ror.org/01wspv808

Funder(s)

Funder type
Research organisation

Funder Name
British Society for Haematology (BSH) (UK)

Alternative Name(s)
BSH

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

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?
Results article	results	01/02/2015		Yes	No