

Norfolk Platelet And Stroke Study (PASS)

Submission date 11/02/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 18/07/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 16/03/2017	Condition category Circulatory System	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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

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KRISTIAN.BOWLES@nnuh.nhs.uk

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

Platelet function result at time of stroke/TIA

Key secondary outcome(s)

Measured at at 90 days and 1 year:

1. Re-stroke
2. Other vascular event
3. Death

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Study participating centre

Colney Lane

Norwich

United Kingdom

NR4 7UY

Sponsor information

Organisation

Norfolk and Norwich University Hospital NHS Foundation Trust (UK)

ROR

<https://ror.org/01wspv808>

Funder(s)

Funder type

Research organisation

Funder Name

British Society for Haematology (BSH) (UK)

Alternative Name(s)

The British Society for Haematology (BSH), BSH

Funding Body Type

Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

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?
Results article	results	01/02/2015		Yes	No