

# The influence of low dose aspirin therapy on perioperative primary haemostasis in patients with vascular disease undergoing orthopaedic surgery

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 02/05/2012	<b>Condition category</b> Haematological Disorders	<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 Julian Sonksen

### Contact details

Department of Anaesthetics  
Russells Hall Hospital  
Dudley  
United Kingdom  
DY1 2HQ

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

### Secondary identifying numbers

N0557093705

# Study information

## Scientific Title

## Study objectives

How long does it take for the bleeding time to return to normal after stopping aspirin?

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Study design

Randomised double blind placebo controlled trial.

## Primary study design

Interventional

## Secondary study design

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

Haemostasis

## Interventions

Each patient receives three containers of tablets (5+3+2) containing either aspirin or placebo.

Random allocation to:

1. 10 days aspirin
2. 8 days aspirin + 2 days placebo
3. 5 days aspirin + 5 days placebo
4. 10 days placebo

## Intervention Type

Drug

## Phase

Not Specified

**Drug/device/biological/vaccine name(s)**

aspirin

**Primary outcome measure**

Bleeding times on day of recruitment, morning of surgery and after surgery.

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/10/2000

**Completion date**

31/10/2004

## Eligibility

**Key inclusion criteria**

100 Patients undergoing orthopaedic surgery.

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

100

**Key exclusion criteria**

Does not meet inclusion criteria

**Date of first enrolment**

01/10/2000

**Date of final enrolment**

31/10/2004

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**  
**Department of Anaesthetics**  
Dudley  
United Kingdom  
DY1 2HQ

## **Sponsor information**

**Organisation**  
Department of Health (UK)

**Sponsor details**  
Richmond House  
79 Whitehall  
London  
United Kingdom  
SW1A 2NL

**Sponsor type**  
Government

**Website**  
<http://www.doh.gov.uk>

## **Funder(s)**

**Funder type**  
Hospital/treatment centre

**Funder Name**  
The Dudley Group of Hospitals NHS Trust (UK)

## **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?
<a href="#">Results article</a>	results	01/03/1999		Yes	No