

# DASH trial

## Desmopressin for reversal of Antiplatelet drugs in Stroke due to Haemorrhage

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ISRCTN 67038373

### Randomisation form v1.1

#### Section A: Inclusion/exclusion criteria and consent

##### Inclusion criteria

- Adults (at least 18 years old) with confirmed intracerebral haemorrhage on imaging
- Event less than 24 hours from onset of symptoms, or from when last seen free of stroke symptoms (for sleep stroke, take onset as bed time)
- Prescribed and thought to be taking a daily oral antiplatelet drug in the preceding seven days – Aspirin, Dipyridamole, Clopidogrel, Prasugrel (Efient®) and/or Ticagrelor (Brilique®).

##### Exclusion criteria

- Aneurysmal subarachnoid haemorrhage known at time of randomisation
- Haemorrhage suspected to be due to transformation of ischaemic stroke or trauma
- Haemorrhage known to be due to thrombolytic drug or venous thrombosis
- Risk(s) of fluid retention associated with desmopressin judged clinically significant by the attending physician (for example patients with pulmonary oedema and/or cardiac failure)
- Significant hypotension (systolic blood pressure under 90 mmHg)
- Known drug-eluting coronary artery stent in previous three months
- Allergy to desmopressin
- Pregnant or breastfeeding
- Life expectancy less than four hours, or planned for palliative care only
- Severe pre-morbid disability (modified Rankin scale is 5)
- Glasgow coma scale less than 5
- Geographical or other factors that prohibit follow-up at 90 days, e.g. no fixed address or telephone contact number, or overseas visitor

A1	Have the eligibility criteria been fulfilled?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
A2	Has appropriate consent been obtained?	<input type="checkbox"/> Yes <input type="checkbox"/> No	

#### Section B: Participant details

B1	Date of data collection ( <i>dd-mmm-yyyy</i> )	D ____ / M ____ / Y ____	
B2	Initials  <i>3 letters from forenames then surname, or 2 separated by a hyphen (-)</i>	<input type="text"/>	
B3	Date of birth ( <i>dd-mmm-yyyy</i> )	D ____ / M ____ / Y ____	
B4	Sex	<input type="checkbox"/> Male <input type="checkbox"/> Female	

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Hospital number	C	Trial number		Sex	Investigator	
Date of collection	d /m /y	Initials		Date of birth	d /m /y	Signature

B5	Date/time of onset of index stroke ( <i>dd-mmm-yyyy hh:mm 24hr</i> )	D ____ / M ____ / Y ____ H ____ : M ____	
B6	Blood pressure readings	Systolic / Diastolic (mmHg)	
B6a	Reading 1	_____ / _____	
B6b	Reading 2	_____ / _____	<input type="checkbox"/> Not done <input type="checkbox"/> Not known
B7	Intra-ventricular haemorrhage on CT scan?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Not known

**History of antiplatelet therapy on admission**

B8a	Aspirin	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Not known
B8b	Dipyridamole	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Not known
B8c	Clopidogrel	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Not known
B8d	Prasugrel (Efient®)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Not known
B8e	Ticagrelor (Brilique®)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Not known

**Section C: Modified Rankin Scale (pre-stroke)**

C1	Modified Rankin Scale (pre-stroke)	<input type="checkbox"/> 0 - No symptoms at all <input type="checkbox"/> 1 - No significant disability, despite symptoms <input type="checkbox"/> 2 - Slight disability <input type="checkbox"/> 3 - Moderate disability <input type="checkbox"/> 4 - Moderately severe disability <input type="checkbox"/> 5 - Severe disability	
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**Section D: Glasgow coma scale**

D1	Eye movement	<input type="checkbox"/> 1 - None <input type="checkbox"/> 2 - To pain <input type="checkbox"/> 3 - To speech <input type="checkbox"/> 4 - Spontaneous	
D2	Motor response	<input type="checkbox"/> 1 - None <input type="checkbox"/> 2 - Extension <input type="checkbox"/> 3 - Flexor response <input type="checkbox"/> 4 - Withdrawal <input type="checkbox"/> 5 - Localises pain <input type="checkbox"/> 6 - Obeys commands	
D3	Verbal response	<input type="checkbox"/> 1 - None <input type="checkbox"/> 2 - Incomprehensible <input type="checkbox"/> 3 - Inappropriate	

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<b>Date of collection</b>	d /m /y	<b>Initials</b>		<b>Date of birth</b>	d /m /y	<b>Signature</b>

	<input type="checkbox"/> 4 - Confused <input type="checkbox"/> 5 - Orientated	
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<b>Section E: Randomisation details</b>		
E1	Date/time of randomisation ( <i>dd-mm-yyyy hh:mm 24hr</i> )	D ____ / M ____ / Y ____ H ____ : M ____
E2	Allocated treatment pack ID	

<b>Please ensure that the correct treatment pack is prescribed on the participant's drug chart</b>	
Are any values missing due to tests not done (or measures not taken), or because data are unknown and every effort has been made to find the data – i.e. 'Not done' / 'Not known'?	<input type="radio"/> Yes <input type="radio"/> No
Comments  If any values are missing, please provide a <u>full</u> explanation	<div style="border: 1px solid black; height: 100px;"></div>

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<b>Date of collection</b>	d /m /y	<b>Initials</b>		<b>Date of birth</b>	d /m /y	<b>Signature</b>