DASH trial
Desmopressin for reversal of Antiplatelet drugs in Stroke due to Haemorrhage

ISRCTN 67038373

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Protocol violation form v1.1

Section A: Protocol violation details

A1 Type of protocol violation

Baseline characteristics

- ☐ Randomisation over 12 hours from onset of symptoms
- ☐ Participant less than 18 years of age
- ☐ Pre-morbid dependency (mRS of 5)
- ☐ Aneurysmal subarachnoid haemorrhage known at time of randomisation
- ☐ Haemorrhage suspected to be due to transformation of ischaemic stroke
- ☐ Haemorrhage known to be due to thrombolytic drug
- ☐ Haemorrhage known to be due to venous thrombosis
- ☐ Clinically significant risk(s) of fluid retention associated with desmopressin
- ☐ Significant hypotension prior to randomisation (systolic BP under 90 mmHg)
- ☐ Known drug-eluting coronary artery stent in previous three months
- ☐ Randomising event was secondary to trauma
- ☐ Glasgow Coma Scale less than 5
- ☐ Known probable life expectancy of less than 4 hours, or planned for palliative care only
- ☐ Female patient pregnant or breastfeeding
- ☐ Not a primary intracerebral haemorrhage, known at time of randomisation
- ☐ Existing contra-indication to desmopressin known at time of randomisation

Practice during the trial

- ☐ Participant does not receive all of the randomised treatment as per protocol
- ☐ Failure to complete SAEs where appropriate
- ☐ Failure to complete outcomes where appropriate
- ☐ Failure to check serum sodium 24±8 hours after infusion of IMP

Consent and re-consent

- ☐ Failure to obtain any consent - neither brief information sheet/assent nor fully informed consent
- ☐ Failure to obtain appropriate, fully informed consent (following brief or independent physician consent)
- ☐ Individual taking consent not authorised to take consent on delegation log
- ☐ Wrong consent form used to obtain fully informed consent

Management of IMP (non-participant records)

- ☐ Treatment pack lost
- ☐ Treatment pack exposed to a temperature excursion

Miscellaneous

- ☐ Any other major violation of the trial protocol

A2	Full explanation / comments	