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

ISRCTN 67038373

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# Serious Adverse Event form v1.1

After the first 7 day period, please remember that only fatal SAEs and safety outcome events – hyponatraemia (low sodium), hypervolaemia (fluid overload), seizures, VTE (DVT and/or PE), ischaemic stroke, TIA, MI/ACS and/or PAD – need to be reported.
There should only be one event that records (the primary cause of) death.

Medically important events should only be reported if they may jeopardise the participant, and may require medical or surgical intervention to prevent one of the outcomes listed in the SAE definition.
Adverse events (such as exacerbation of pre-existing illness) do not need expediting reporting.

| | | | |
|---|---|---|---|
| **Section A: Event information** | | | |
| A1 | Date and time began *(dd-mmm-yyyy hh:mm 24hr)* | D _____ / M _____ / Y _____<br>H _____ : M _____ | |
| A2 | Date and time reported to investigator *(dd-mmm-yyyy hh:mm 24hr)* | D _____ / M _____ / Y _____<br>H _____ : M _____ | |
| A3 | When did this event happen with regard to the treatment? | ☐ Before<br>☐ During<br>☐ After | |
| A4 | Please describe the event, e.g. new limb weakness, crushing chest pain, bleeding gums, rash<br><br>**Note: Death is an end result, not an independent event** | | |
| A5a | Please sub-categorise the event Please only enter a code/description from the SAE sub-category list | | |
| A5b | If 'other', please state the medical condition (diagnosis, not treatment) | | ☐ Not applicable |
| A6 | Nature of event | ☐ Single episode<br>☐ Multiple episodes | |
| A7 | Intensity of event | ☐ Mild<br>☐ Moderate<br>☐ Severe | |
| **Did any of the following events occur?** | | | |
| A8a | If the participant has died, was this event the primary cause of death? | ☐ Yes<br>☐ No | |
| A8b | If yes, please enter date of death *(dd-mmm-yyyy)* | D _____ / M _____ / Y _____ | ☐ Not applicable |
| A8c | Life threatening | ☐ Yes<br>☐ No | |
| A8d | Hospitalisation or hospitalisation prolonged | ☐ Yes<br>☐ No | |

| | | | |
|---|---|---|---|
| A8e | Persistent or significant disability/incapacity | ☐ Yes<br>☐ No | |
| A8f | Congenital anomaly/birth defect | ☐ Yes<br>☐ No | |
| A8g | Medically important | ☐ Yes<br>☐ No | |
| A9a | If hospitalised, start date of hospitalisation *(dd-mmm-yyyy)* | D _____ / M _____ / Y _____ | ☐ Not applicable<br>☐ Not known |
| A9b | If hospitalised, end date of hospitalisation *(dd-mmm-yyyy)* | D _____ / M _____ / Y _____ | ☐ Not applicable<br>☐ Not known |
| A10a | Relationship to study drug | ☐ Not related<br>☐ Improbable<br>☐ Possible<br>☐ Probable<br>☐ Definite | |
| A10b | Please classify the event | ☐ Serious adverse reaction - SAR<br>☐ Expected event - SAE<br>☐ Unexpected reaction - SUSAR<br>**Please assess if expected according to SmPC https://medicines.org.uk/emc/product/5447/smpc** | |
| A10c | Causality – detail possible suspected causes | | |
| A11a | Action taken regarding study drug, if related | ☐ Continued<br>☐ Dose interrupted<br>☐ Discontinued | ☐ Not applicable |
| A11b | If discontinued or interrupted, date and time dose was stopped *(dd-mmm-yyyy hh:mm 24hr)* | D _____ / M _____ / Y _____<br>H _____ : M _____ | ☐ Not applicable<br>☐ Not known |
| A12a | Clinical outcome of this event | ☐ Resolved<br>☐ Event ongoing<br>☐ Recovered with sequelae<br>☐ Died | |
| A12b | If 'Event ongoing' or 'Recovered with sequelae', please provide details | | ☐ Not applicable |

**Section B: Diagnostic evidence**

**Please provide details of all available diagnostic evidence / results relevant to the event**

| | | | |
|---|---|---|---|
| B1 | Pathological | | ☐ Not applicable<br>☐ Not done<br>☐ Not known |
| B2 | CT/MRI head | | ☐ Not applicable<br>☐ Not done<br>☐ Not known |

| | | | |
|---|---|---|---|
| B3 | Other radiological | | ☐ Not applicable<br>☐ Not done<br>☐ Not known |
| B4 | ECG *(please fax to 0115 823 1771)* | | ☐ Not applicable<br>☐ Not done<br>☐ Not known |
| B5 | Bacteriology | | ☐ Not applicable<br>☐ Not done<br>☐ Not known |
| B6 | Biochemistry | | ☐ Not applicable<br>☐ Not done<br>☐ Not known |
| B7 | Haematology | | ☐ Not applicable<br>☐ Not done<br>☐ Not known |
| B8 | Clinical | | ☐ Not applicable<br>☐ Not done<br>☐ Not known |
| B9 | Other | | ☐ Not applicable<br>☐ Not done<br>☐ Not known |
| B10 | Comments | | ☐ Not applicable |

**Please check your entries thoroughly.**

**If a post-mortem/autopsy has been performed, please FAX through a copy (anonymised with centre number, trial number, participant initials) to 0115 823 1771.**

| | |
|---|---|
| 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'? | ○ Yes ○ No |
| Comments<br><br>If any values are missing, please provide a full explanation | |