Clinical trial results:
Desmopressin for reversal of Antiplatelet drugs in Stroke due to Haemorrhage (DASH)

Summary

EudraCT number	2018-001904-12
Trial protocol	GB
Global end of trial date	09 June 2022

Results information

Result version number	v1 (current)
This version publication date	08 July 2023
First version publication date	08 July 2023
Summary attachment (see zip file)	DASH RfPB final report (PB-PG-0816-20011-Final Report-22_12_2022 15_07_44.pdf) DASH protocol paper (DASH protocol paper BMJ open.pdf) Publication (1-s2.0-S1474442223001576-main.pdf)

Trial information

Trial identification

Sponsor protocol code	18040

Additional study identifiers

ISRCTN number	ISRCTN67038373
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	University of Nottingham
Sponsor organisation address	Queens Medical School Campus, Nottingham, United Kingdom, NG7 2UH
Public contact	Sprigg, University of Nottingham, 44 115 82 31765, nikola.sprigg@nottingham.ac.uk
Scientific contact	Sprigg, University of Nottingham, 44 115 82 31765, nikola.sprigg@nottingham.ac.uk

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	01 September 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	09 June 2022
Global end of trial reached?	Yes
Global end of trial date	09 June 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the feasibility of randomising, administering the intervention, and completing follow-up for patients treated with desmopressin or placebo to inform a definitive trial.

Protection of trial subjects:

An independent data monitoring committee reviewed the data during the trial.

Background therapy:

Standard care for ICH as per local clinical guidelines

Evidence for comparator:

Placebo (saline) is comparator

Actual start date of recruitment	01 August 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 54
Worldwide total number of subjects	54
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	11
From 65 to 84 years	33
85 years and over	10

Subject disposition

Recruitment

Recruitment details:

Participants were recruited from ten acute stroke centres in the United Kingdom. Participants were included if they met all the inclusion criteria and none of the exclusion criteria.

Pre-assignment

Screening details:

Patients with acute stroke due to ICH screen by site staff

Period 1

Period 1 title	Baseline (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer, Assessor

Blinding implementation details:

All blinded to allocation.

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Control (saline)

Arm type	Placebo
Investigational medicinal product name	Saline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for injection/infusion
Routes of administration	Injection

Dosage and administration details:

Saline

Arm title	Desmopressin

Arm description:

Desmopressin

Arm type	Experimental
Investigational medicinal product name	Desmopressin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for concentrate for solution for infusion
Routes of administration	Infusion

Dosage and administration details:

Tbc

Number of subjects in period 1	Placebo	Desmopressin
Started	27	27
Completed	27	27

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description: Control (saline)	
Reporting group title	Desmopressin
Reporting group description: Desmopressin	

Reporting group values	Placebo	Desmopressin	Total
Number of subjects	27	27	54
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	6	5	11
From 65-84 years	17	16	33
85 years and over	4	6	10
Gender categorical			
Gender			
Units: Subjects			
Female	7	11	18
Male	20	16	36

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description: Control (saline)	
Reporting group title	Desmopressin
Reporting group description: Desmopressin	

Primary: modified rankin day 90 dichotomy

End point title	modified rankin day 90 dichotomy[1]
End point description: mRS > 4	
End point type	Primary
End point timeframe: day 90	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Feasibility trial so no formal statistical analysis was carried out

End point values	Placebo	Desmopressin		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	27	27		
Units: dead or severly dependent				
mRS>4	10	6		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: 90 days	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	25.0

Reporting groups	
Reporting group title	Placebo
Reporting group description: Control (saline)	
Reporting group title	Desmopressin
Reporting group description: Desmopressin	

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: Non SAE's were not collecected as per protocol

Serious adverse events	Placebo	Desmopressin	
Total subjects affected by serious adverse events			
subjects affected / exposed	13 / 27 (48.15%)	12 / 27 (44.44%)	
number of deaths (all causes)	7	5	
number of deaths resulting from adverse events	0	0	
General disorders and administration site conditions			
All SAEs			
subjects affected / exposed	13 / 27 (48.15%)	12 / 27 (44.44%)	
occurrences causally related to treatment / all	1 / 22	3 / 16	
deaths causally related to treatment / all	0 / 7	0 / 5	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Placebo	Desmopressin	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
22 November 2019	SA/03/19, 22/11/2019, participants could be recruited if they could be randomised within 24 hours from onset of symptoms.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

This was a feasibility trial that took place in the COVID 19 pandemic.
No statistical comparisons were performed due to lack of power, as per protocol.
Full report is available in the End of Trial Funder Report - see attached.
Paper to be uploaded

Notes: