

East Midlands - Nottingham 2 Research Ethics Committee

Equinox House
City Link
Nottingham
NG2 4LA

20 September 2021

Dr Nikola Sprigg
Clinical Associate Professor
University of Nottingham
Clinical Sciences Building, City Hospital Campus
Hucknall Road
Nottingham
NG5 1PB

Dear Dr Sprigg

Study title: Desmopressin for reversal of Antiplatelet drugs in Stroke due to Haemorrhage (DASH)
REC reference: 18/EM/0184
Protocol number: 18040
EudraCT number: 2018-001904-12
Amendment number: SA_04_21
Amendment date: 04 July 2021
IRAS project ID: 233744

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Completed Amendment Tool [SA_04_21 Locked amendment tool]	1.5 25 Mar 2021	04 July 2021
IRAS Application Form [Updated IRAS form]	Version 5.20	01 June 2018
Summary CV for Chief Investigator (CI) [Chief Investigator CV]	1	16 August 2021

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you have not already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

Statement of compliance

This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: <https://www.hra.nhs.uk/planning-and-improving-research/learning/>

IRAS Project ID - 233744:

Please quote this number on all correspondence

Yours sincerely

pp. Frank Macdonald
Approvals Administrator

Dr Ian Ross
Chair

E-mail: nottingham2.rec@hra.nhs.uk

Enclosures: List of names and professions of members who took part in the review

Copy to: Ms Angela Shone

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Attendance at Sub-Committee of the REC meeting

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mr Daniel (Ben) Kennedy	Consultant Haematologist/Honorary Associate Professor	Yes	
Dr Ian Ross (Chair)	Retired Consultant Physician	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mr Frank Macdonald	Approvals Administrator