

East Midlands - Leicester Central Research Ethics Committee

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Stratford
London
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Tel: 02071048227

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

31 August 2023

KAILASH KRISHNAN
Nottingham University Hospitals NHS Trust
Derby Road
Nottingham
NG7 2UH

Dear Dr Krishnan

Study title: MAⁿnitol for Cerebral oEdema after IntraCerebral Haemorrhage (MACE-ICH): a feasibility trial
REC reference: 22/EM/0242
Protocol number: 22SR001
EudraCT number: 2022-000283-22
Amendment number: SA_01_23
Amendment date: 30 June 2023
IRAS project ID: 1004870

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>
Amendment Summary [AmendmentSummary]		04 August 2023
Annex 2: Notification of Amendment/Amendment tool [SA_01_23 Amendment tool]	1	30 June 2023
Cover Letter [SA_01_23 Cover letter]	1	03 August 2023
Other [mCTA (tracked changes)]	4	23 June 2023
Other [mCTA]	4	23 June 2023
Participant information and informed consent form [Legal representative consent form (tracked changes)]	2.0	27 July 2023
Participant information and informed consent form [Legal representative consent form]	2.0	27 July 2023
Participant information and informed consent form [Participant consent form (tracked changes)]	2.0	27 July 2023
Participant information and informed consent form [Participant consent form]	2.0	27 July 2023
Participant information and informed consent form [Legal representative pictorial information sheet and consent (tracked changes)]	2.0	27 July 2023
Participant information and informed consent form [Legal representative pictorial information sheet and consent]	2.0	27 July 2023
Participant information and informed consent form [Legal representative information sheet (tracked changes)]	2.0	27 July 2023
Participant information and informed consent form [Legal representative information sheet]	2.0	27 July 2023
Participant information and informed consent form [Participant pictorial information sheet and consent (tracked changes)]	2.0	27 July 2023
Participant information and informed consent form [Participant pictorial information sheet and consent]	2.0	27 July 2023
Participant information and informed consent form [Participant information sheet (tracked changes)]	2.0	27 July 2023
Participant information and informed consent form [Participant information sheet]	2.0	27 July 2023
Project Information - PDF [ProjectStudyInformation]		04 August 2023
Protocol [Protocol (tracked changes)]	2.0	27 July 2023
Protocol [Protocol]	2.0	27 July 2023
REC Application Form [Ethics]		04 August 2023
Validated questionnaire [Participant month 6 follow up questionnaire]	1.1	21 June 2023

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

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 - 1004870:	Please quote this number on all correspondence
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Yours sincerely



PP

Mrs Rita Patel
Chair

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

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

Copy to:

East Midlands - Leicester Central Research Ethics Committee

Attendance at Sub-Committee of the REC meeting held in correspondence.

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mrs Susan Allen	Director of Management Training Consultancy	Yes	
Mrs Rita Patel (Chair)	Retired Contracts and Innovation Manager	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Ms Tracy Hamrang	Approvals Administrator