



Health Research Authority

East Midlands - Nottingham 2 Research Ethics Committee

Health Research Authority
Redman Place
Stratford
E20 1JQ

15 August 2024

Professor Christine Roffe
Co-Investigator/Consultant Stroke Physician
University Hospitals of North Midlands NHS Trust

Dear Professor Roffe

Study title: The Metoclopramide for Avoiding Pneumonia after Stroke (MAPS-2) Trial: a single-blind, randomized controlled trial of metoclopramide for the prevention of pneumonia in patients with dysphagia after an acute stroke

REC reference: 21/EM/0246

Protocol number: 21051

EudraCT number: 2021-003853-40

Amendment number: SA-03-24

Amendment date: 24 July 2024

IRAS project ID: 290474

The above amendment was reviewed at the meeting of the Sub-Committee held on 12 August 2024 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 [290474 SA-03-24]	Amendment Tool v1.6 06 December 2021	24 July 2024
Cover Letter [MAPS-2 Cover Letter MHRA draft 24.07.24]	1	24 July 2024
Financial Arrangements [PO 4635216]	1	18 July 2024
Research protocol or project proposal [MAPS-2 Research Protocol v2.0 20240702 - tracked resubmission _24.07.24]	v2.0 resubmission	02 July 2024

Research protocol or project proposal [MAPS-2 Research Protocol v2.0 20240702 - clean]	v2.0 resubmission	02 July 2024
Research protocol or project proposal [MAPS-2 Research Protocol v1.1_20220628_Clean]	v1.1	28 June 2022
Research protocol or project proposal [MAPS-2 Research Protocol v1.1_20220628_tracked-changes]	v1.1	28 June 2022
Research protocol or project proposal [MAPS-2 Research Protocol v1.2_20220713_clean]	v1.2	13 July 2022
Research protocol or project proposal [MAPS-2 Research Protocol v1.2_20220713_tracked-changes]	1.2	13 July 2022
Research protocol or project proposal [MAPS-2 Research Protocol v1.3 20221108 clean copy]	1.3	08 November 2022
Research protocol or project proposal [MAPS-2 Research Protocol v1.3_20221108_tracked changes]	1.3	08 November 2022
Research protocol or project proposal [MAPS-2 Research Protocol v1.4_20230306_Clean (11)]	1.4	06 March 2023
Research protocol or project proposal [MAPS-2 Research Protocol v1.4_20230306_TC]	1.4	06 March 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

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 - 290474:

Please quote this number on all correspondence

Yours sincerely

Ms Bernadette Roberts
Chair

Pp. Sean May
Approvals Administrator

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

East Midlands - Nottingham 2 Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 12 August 2024

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mrs Leanne Morgan	Grants Development Manager	Yes	
Ms Bernadette Roberts	Retired Finance Manager	Yes	Chair

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mr Sean May	Approvals Administrator