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Subject: FW: MAPS-2 Newsflash - April 2021

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MAPS-2 NEWSFLASH | APRIL 2021

MAPS-2

Metoclopramide for Avoiding Pneumonia after Stroke (MAPS-2)

NEWSFLASH

UPDATE: We are delighted to announce that MAPS-2 has now been awarded funding by the NIHR HTA.

EXPRESSION OF INTEREST

If you are still interested in taking part in the MAPS-2 study, please click the link below which will take you to a form to

fill in required details:

https://forms.office.com/r/9Lasf5yq8Q

Please ensure to complete it only once per site - thank you!

DEADLINE: 30th April 2021

TIMELINE - IMPORTANT DATES

GRANT START: 01 May 2021

APPROVALS & SETUP: between May 20201 & August 2021

RECRUITMENT START: from start of late 2021 (Q2/Q3)

TRIAL SUMMARY

BACKGROUND: Stroke is the most common cause of death worldwide and the foremost cause of complex disability in the UK. Pneumonia causes more deaths after stroke than the neurological damage itself. Stroke-associated pneumonia is caused by aspiration of vomited and regurgitated gastric content. Metoclopramide, an antiemetic with both central and peripheral actions, was associated with less pneumonia and a trend to fewer deaths in our pilot study.

AIM: To determine whether metoclopramide, given early after the stroke, can reduce pneumonia and deaths.

SETTING: Emergency departments and stroke units of 90 or more NHS hospitals in the UK.

INCLUSION CRITERIA:
1. Adult patients admitted to hospital with a diagnosis of acute stroke **and**
2. Within 9 hours of symptom onset **and**
3. Moderate to severe neurological impairment (NIHSS 10 or greater) **and**
4. Dysphagia (assessed by bedside clinical screen)

EXCLUSION CRITERIA:
1. Probable or definite pneumonia at screening

2. Contraindications to metoclopramide
3. Pregnant or breast feeding
4. Co-morbid conditions with life expectancy <3 months
5. Inability to gain consent (patient or legal representative) or consent declined

INTERVENTION:

Intervention: Metoclopramide solution for injection 10 mg/2 ml three times a day by slow IV injection or via nasogastric tube. For participants weighing less than 60 kg the dose will be reduced to 5 m three times a day.

Control: Normal saline solution for injection (sham control) 2 ml three times a day by slow intravenous injection or via nasogastric tube.

Trial treatment will be continued for 14 days or until discharge from hospital, whichever is earlier.

RECRUITMENT TIMELINE: We will be recruiting participants for 3 years.

CONSENT: We are seeking Ethical approval for rapid emergency consent process, with verbal permission obtained to administer the IMP, followed later by a written consent.

FOLLOW-UP: There will be local follow-up at day 14 (or death/discharge from hospital if sooner) & centrally at 6 months (by post or telephone by the coordinating centre).

For any queries, email:

MS-MAPS-2@exmail.nottingham.ac.uk

SUPPORTED BY NIHR | National Institute for Health Research

MAPS-2

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