



🔰 @Maps2trial

Metoclopramide for Avoiding Pneumonia after Stroke: MAPS-2

Happy Summer from Nottingham STU!

Site Update:





Recent Activations:

- + Norfolk and Norwich University Hospital, Norwich
- + University Hospital Monklands, Airdrie
- + James Cook University Hospital, Middlesbrough
- + Countess of Chester Hospital, Chester
- + Addenbrooke's Hospital, Cambridge
- + Northwick Park Hospital, Harrow
- + New Cross Hospital, Wolverhampton

Associate Pls:

MAPS-2 is part of the NIHR'S Associate PI scheme! If you would like to register as an associate PI for this study, use the below link to register:

https://docs.google.com/forms/d/e/1FAIpQLScv5XTwVbbRNXhru1jDU70u1bE8xw3UaHW2XCoYmQ4FIXgcvQ/viewform

Applicants MUST register and have this confirmed before they can act as an associate PI in MAPS-2.

Amendments:

All amendments documentation is available on our website:

MA/01/21 - Approved 01/12/2021 MA/02/22 - Approved 11/02/2021 MA/03/22 - Approved 03/05/2022 MA/04/22 (protocol v1.1) - Approved 29/06/2022 MA/05/22 (protocol v1.2) - Approved 13/07/2022 FAQs:



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Q: Can oral liquid metoclopramide be used down the NG tube?

A: No - it must be the IV prep due to different consistency - oral liquid is syrupy and would be easily identifiable to the patient, therefore almost impossible to keep treatment blinded.

Q. How far back in medical history is gastric bleeding an exclusion?

A: Acute gastric bleeding within past 2 weeks.

Q: Day 14 assessment: is there any leeway, if falls at weekend, staff not always able to cover weekends, can they do the assessment ± 1 or 2 days?

A: Yes, mainly the NIHSS score that is time critical and has to be done on the day, the rest can be ascertained from the notes equally well or assessment can be done on the Friday if discharge known to be at the weekend.

Q: Do you have to be on the delegation log to prescribe the IMP?

A: Yes. However, being on the delegation log is not require to <u>deliver</u> the IMP.

Q: Is the mRS score an inclusion criteria?

A: No

Q: If patient's renal function appears to be normal and they are eligible for trial participation, but then deteriorates during the trial – are they withdrawn?

A: Not if it was normal at the start - can do a dose adjustment if severe deterioration but ultimately it would be the decision of the treating clinician.

Q: Epilepsy is an exclusion but what if patients come in with stroke-induced seizures?

A: If actively fitting at time of screening then they would not be included. If they've passed the inclusion criteria and been randomised, then have a stroke-induced seizure- they are kept in the trial and the event is recorded.

Q: Can you co-enrol the participant into another trial after the participant has finished the 14 days treatment but before the 6 month follow-up?

A: No, not until after the MAPS-2 trial 6 month follow up (as per protocol), unless it is just an observational study with no interventions.

Q: If patients are admitted with a Percutaneous endoscopic gastrostomy -(PEG line) – can they participate in the trial ?

A: Yes - can administer dose down PEG line.

Q: If a patient is randomised to the placebo arm but then requires antiemetics, can the clinician prescribe PRN metoclopramide for 1 or 2 doses?

A: No, this will compromise the integrity of the results. Please use alternative antiemetics.

Further Questions? Give us a call! 0115 823 1665