



Metoclopramide for Avoiding Pneumonia after Stroke: MAPS-2

We are now recruiting!

A huge congratulations to **Royal Stoke University Hospital** for being the **first** site open!

Recent Green Lights



Whiston Hospital - St Helens & Knowsley Teaching Hospitals NHS Trust

Recruitment Update: 1

A huge congratulations to the research team at Royal Stoke University Hospital for recruiting the **first** patient!

Trial Training:

All MAPS-2 trial-specific training will be performed **remotely.** Please get in touch with one of us if your site is ready to schedule a training date! We will do our best to accommodate the dates that suit your availability:

MAPS-2@nottingham.ac.uk Cameron.Skinner1@nottingham.ac.uk Lesia.Kurlak@nottingham.ac.uk

All MAPS-2 training sessions are expected to last approximately 1hour & 15 minutes (including questions!).

Amendments:

Approved amendments:

MA/01/21 - Approved 01/12/2021 MA/02/22 - Approved 11/02/2021

We are planning to submit MA/03/21 in the near-future - this will be sent to you when available!





Common FAQs:

What is the planned recruitment end date and study end date?

Recruitment end date: 30th October 2024. Study end date: 30th April 2025

Is there a pharmacy manual?

No - all IMP information is detailed in the protocol and metoclopramide SmPC.

Who can consent patients in MAPS-2?

Both medics and non-medics may take consent. Consenting investigators must explain the trial to patients, elaborate on the risks and potential benefits and be able to answer any trial-specific questions. <u>However, eligibility must be completed and signed off by</u> <u>a medic.</u>

Do investigators need to be GCP-trained to prescribe the medication? Yes.

Do investigators need to be GCP-trained in order to administer the medication?

No. The treatment can be administered by non-GCP-trained ward nurses, however, staff must be GCP-trained in order to complete the CRFs & enter data into the database.

Are sites required to submit chest x-ray images centrally?

No, we are only requesting the reports. These will be uploaded via our MAPS-2 bespoke system.

Why is there a cost for uploading radiological images in the contract?

MAPS-2 was initially going to request chest x-ray images for all patients, however it was decided that this may be too burdensome for sites. The cost has remained in the contract just in case any images are required to review any relevant SAEs or SUSARS.

Can the way the method of treatment administration be changed (i.e nasogastric to intravenous or intravenous to nasogastric) throughout the fourteen days?

Yes - the preferred method of IMP administration is via the NG tube, however this may be changed to slow IV injection if the condition of the participant improves.

Can the treatment be given orally, instead of via NG tube or slow IV injection?

No - all treatment must be given via IV or NG route.