



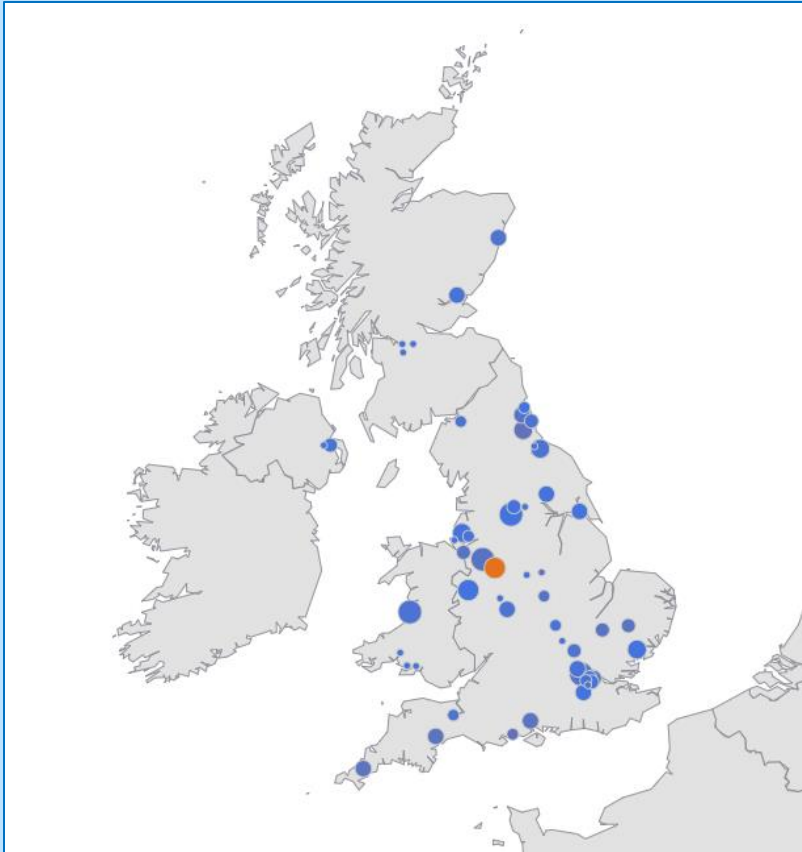
The Metoclopramide for Avoiding Pneumonia after Stroke (MAPS-2) Trial:

**Investigator meeting (13)
28th June 2024**



**University of
Nottingham**
UK | CHINA | MALAYSIA

Recruitment targets and status



Target participant number = 2100

Current enrolment number = 861

Completed follow up at 6 months = 535

No. of recruiting sites open = 68

No. of repatriation sites open = 7

Still looking for new sites both recruiting and repat!

Welcome to new sites! - Heartlands and Good Hope Hospitals, Birmingham

Top 5 Recruiters this month

7	C001: Stoke on Trent
6	C033: Harrow, Northwick Park
3 (First recruits!)	C071: Portadown, Craigavon
2	C031: London, UCLH
2	C039: Watford

THANK
YOU!



June 2024 Recruitment

Great to see these sites back recruiting this month!

C007: Aberdeen, Aberdeen Royal Infirmary

C049: Nottingham, Queen's Medical Centre

C036: Birmingham, Queen Elizabeth Hospital Birmingham

C058: Cramlington (Northumbria)

C015: Liverpool, Aintree Hospital

C060: East Kilbride, University Hospital Hairmyres

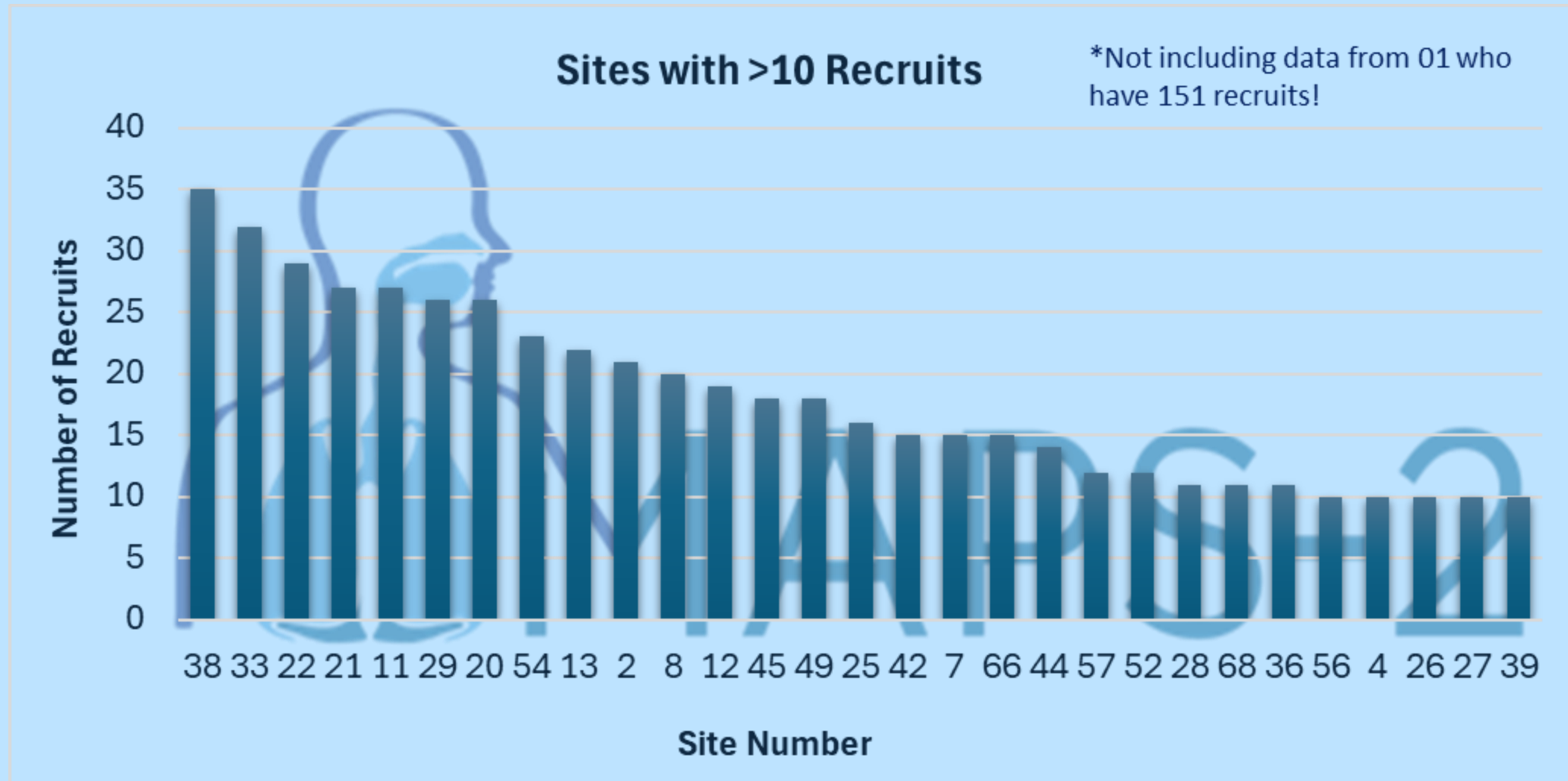
C023: Dundee, Ninewells Hospital & Medical School



C069: Basildon - first recruit this month.

C038: Cambridge, Addenbrooke's Hospital,
C033: Harrow, Northwick Park,
and **C001:** Stoke for consistently recruiting every month so far this year!

Sites with >10 Recruits



Guiding a MAPS-2 consent conversation



1. Why are we doing this study?

- After a stroke, many people have difficulty in swallowing which means that food and drink, or even saliva, may get into their lungs if it can't be coughed up or swallowed. This is called aspiration and can lead to a chest infection called pneumonia.
- More than one in 3 patients with severe stroke develop pneumonia.
- Pneumonia is the most common cause of death after stroke.
- Prevention of pneumonia has the potential reduce deaths and improve recovery after stroke.
- We conducting a clinical study to test a drug which prevents vomiting can reduce pneumonia and deaths after stroke.

Guiding a MAPS-2 consent conversation



2. Why metoclopramide?



- Metoclopramide is a drug which prevents vomiting.
- A small study including 60 patients showed that metoclopramide was safe and reduced pneumonia.
- A larger study is needed to confirm these results.

Metoclopramide side effects as per protocol and patient information leaflet

Very common: Drowsiness

Common: Depression, uncontrollable movements such as tics, twisting movements, muscle rigidity, (symptoms similar to Parkinson's disease) a feeling of restlessness, diarrhoea, low blood pressure, and a feeling of weakness.

Uncommon: allergies, slow heart beats, hallucinations, irregular periods, breast milk production and depressed level of consciousness.

Rare: Confusion and seizures.

Not known: These include involuntary muscle spasms after prolonged use (months), high fevers with muscle rigidity and seizures (neuroleptic malignant syndrome), changes to blood pressure and heart rate which can lead to cardiac arrest, allergic reactions and the development of breasts.

We expect the potential benefit (prevention of pneumonia) to outweigh the very low risk of serious side effects.

	Alteplase	Amlodipine	Metoclopramide	Ibuprofen
Very common more than 1/10	Brain haemorrhage Other haemorrhages Stroke Recurrence Chest pain Heart failure Low blood pressure		Drowsiness	Heartburn Indigestion Stomach pain Sickness Vomiting Flatulence Diarrhoea Constipation
Common 1/10 or less	Haemorrhage -Brain -Throat -Stomach -Bruises -Kidneys and bladder -injection sites Cardiac arrest and shock	Sleepiness Tiredness Weakness Dizziness Headache Visual disturbance Palpitations Breathlessness Ankle swelling Muscle cramps Stomach pain Nausea Indigestion Diarrhoea Constipation Swollen legs	Tiredness Weakness Depression Muscle spasms Parkinson's like symptoms Restlessness Diarrhoea Low blood pressure	Stomach ulcers Vomiting blood Bleeding from bowels Colitis Perforated Bowel Sleepiness Dizziness Agitation Sleeplessness Irritability

Uncommon 1/100 or less	Haemorrhage -Lungs -Nose -Ears Cardiac arrhythmias Heart valve problems	Sleeplessness Anxiety Depression Tremor Taste disturbance Numbness Tingling Tinnitus Cardiac arrhythmias Low blood pressure Cough Runny nose Vomiting Dry mouth Hair loss Bruising Rash Itching Skin discoloration Joint pain Muscle pain Back pain Chest pain Problems passing water Passing water at night Urinary frequency Impotence Feeling unwell Weight Loss Weight gain	Allergies Cardiac arrhythmias Irregular periods Breast milk production Drowsiness	Itchy rash Itching Asthma attack Low blood pressure Visual disturbances Runny nose Bronchospasm Gastritis Leg swelling Kidney problems
Rare 1/1000 or less	Bleeding in other internal organs	Confusion	Confusion and seizures	Blindness Kidney damage Changes in liver function Impaired blood clotting Anaemia

Guiding a MAPS-2 consent conversation



2. What are the risks and benefits?



- Metoclopramide is a drug with an established safety profile which has been used in hospitals for over 40 years in patients with heart attacks, after surgery, and with chemotherapy.
- All medications can cause side effects, but the ones that are common for metoclopramide (e.g. drowsiness, dizziness) are minor and the more serious ones are rare.
- The side effects of this medication are considerably less than those of commonly prescribed blood pressure tablets and over the counter painkillers such as ibuprofen.
- Participation in a clinical trial comes with benefit of additional monitoring by the research team who are primed to look out for side effects of the drugs given.

Informing ward staff about the trial treatment



Importance of blinding



- When doing any trial, it is important to make sure the participants do not know which of the two treatments they are given (drug or placebo). This prevents bias in the results so that they are meaningful.
- In the MAPS-2 trial, this is only possible if the treatment is given IV if an NG is not in place.
- Although you will know whether the patient is taking metoclopramide or placebo it is important that you do not tell the patient or their family, and that you report adverse effects irrespective of which treatment is given.

Any concerns?

- Are there any other concerns that your patients raise about the trial? Please let us know!



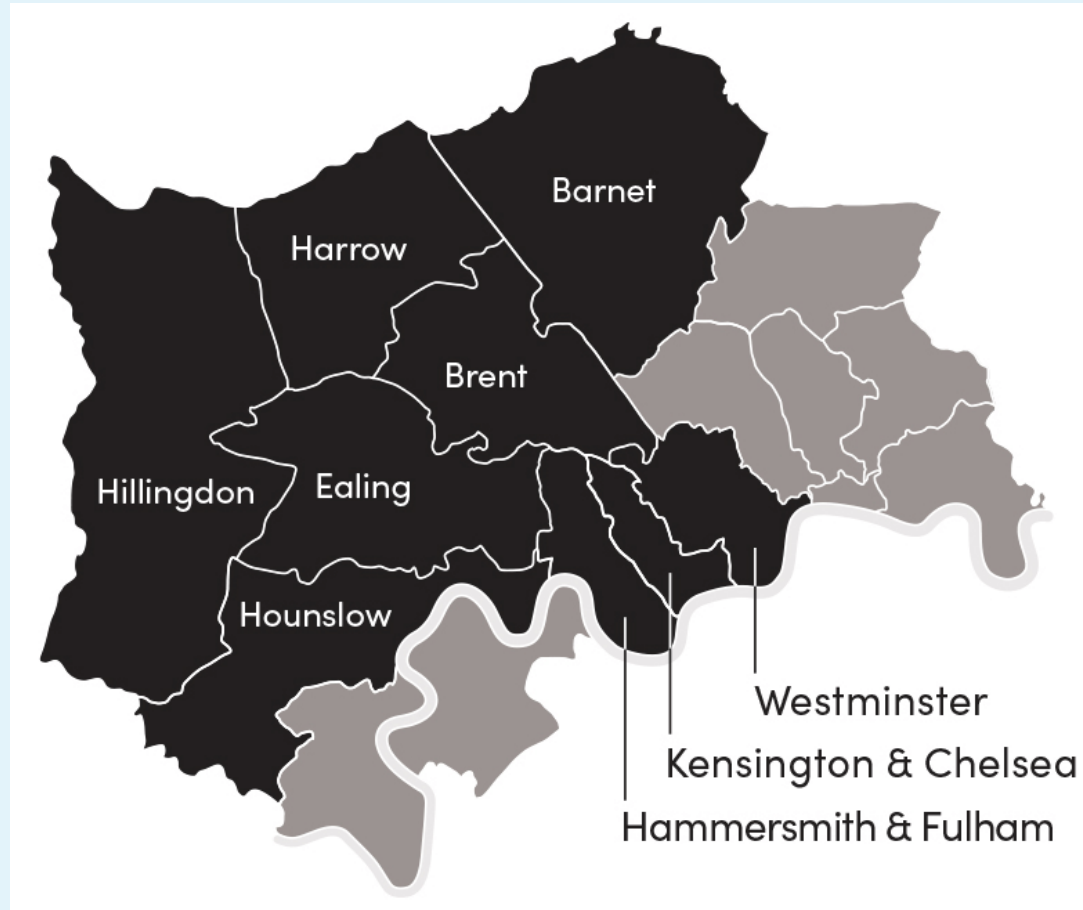
MAPS-2 Team at Northwick Park Hospital Harrow – Northwest London

Pictured:

- **Dr Aravinth (PI)**
- **Tabassum Khan**
(Study Coordinator)
- **Parvathy Gopi**
(Clinical Research Nurse)
- **Sean Connarty**
(Lead RN for Cardiovascular Studies)



Department of Stroke – NPH



- Home to one of the eight HASUs in London
- We receive more than 1500 stroke patients in a year
- Diverse population with all ethnic back grounds

TOP TIPS - NPH

1. SCREENING
2. COMMUNICATION
3. FLEXIBILITY IN WORKING HOURS
4. GOOD HOUSE KEEPING



Open Discussion

