# PARTICIPANT INFORMATION SHEET

*Version 2.1 10th March 2017*

## The Metoclopramide and selective oral decontamination for Avoiding Pneumonia after Stroke (MAPS-2) study

We would like you to take part in this research study. It is important for you to understand what the research is and what it will involve. Please take time to read the information carefully. Talk to others if you wish. Ask if there is anything that is not clear, or if you would like more information.

### What is the purpose of the study?

Pneumonia is a major cause of death after stroke and delays recovery in survivors. It is likely to occur in stroke patients who have lost the ability to swallow safely and need a feeding tube to maintain nutrition. The most important causes of pneumonia in stroke patients are inhalation of saliva or vomit.

Two small studies have shown that prophylactic treatments could reduce pneumonia. The drug metoclopramide, which prevents vomiting, and an antimicrobial paste, which prevents the growth of harmful bugs in the mouth. These studies had promising results, but were too small to be certain that the treatments were effective.

The purpose of this study is to test whether metoclopramide and an antimicrobial mouth paste can prevent death and pneumonia.

### Why have you been chosen?

You have been chosen because you have had a stroke. This has affected your ability to swallow safely. You will be one of over 1,100 patients throughout the UK who are asked to take part in this study.

### Do I have to take part?

No, it is up to you. If you decide to take part, you will be given this information sheet to keep, we will answer any questions you have and then you will be asked to sign a consent form. You are free to withdraw at any time without giving a reason. If you decide not to take part in the study or to withdraw at any time this will not affect the standard of care you will receive.

### What will happen to me if I take part?

The researcher will ask you a few questions and examine your swallow, speech, eyesight, head, arms and legs to determine how the stroke has affected you. You will then be assigned at random to the trial treatments.

These are:

Metoclopramide or matching placebo three times a day

AND

Selective oral decontamination paste or matching placebo applied topically to the gums, tongue and roof of mouth four times a day.

Giving the combinations:

1. Metoclopramide and oral decontaminant paste
2. Metoclopramide and placebo paste
3. Metoclopramide placebo and oral decontaminant paste
4. Metoclopramide placebo and placebo paste

The interventions will be given until nasogastric feeding is no longer required or for a maximum of 21 days.

## What are the drugs being tested?

Metoclopramide is a drug which has been used for many years to prevent sickness and vomiting. It reduces the sensation of sickness in the brain and allows the stomach to empty faster. It is usually prescribed for a few days only, but can be given up to 3 months, if needed.

Selective oral decontamination paste is a yellow paste containing three different antimicrobial agents (colistin, tobramycin, and amphotericin B). These prevent the growth of harmful bacteria in the saliva. The paste is used routinely in intensive care units in the Netherlands and some intensive care units in the UK.

## Will there be any additional assessments or clinic visits?

The trial is planned to run for 23 months from when the first patient is recruited untill the last one is followed up.

For the first 2 weeks of the trial research nurses will record details of your condition, your test results and your medication on a clinical log.

After 4 weeks or when you are discharged from hospital (if this is before 4 weeks) a member of the research team will look at your hospital records and examine you again to find out how you are doing.

After 3 months a member of the MAPS-2 trial team will contact your GP to check on your condition and to confirm your contact details.

A member of the MAPS-2 team will then contact you to find out how well you are recovering from your stroke, and whether you have had any medical problems or

hospital admissions. This will take about 15-30 minutes. If we cannot contact you, we will phone the person(s) you nominated and/or send a letter.

We also ask your permission to check missing information about your health and recovery with the NHS Health and Social Care Information Centre and the Sentinel Stroke National Audit Database.

At the end of the trial we may contact your GP or your hospital to find out how you are doing. If we cannot get all the information we need we may also phone you or a person you nominated as a contact.

You will not have any additional blood tests, X-rays or scans for this study. However, we will collect data from tests and scans conducted as part of your routine clinical care. This will typically include one or two CT head scans and several chest-X-Rays. The radiation you will be exposed to as part of these routine tests is equivalent to approximately 2.5 years of background radiation.

## What are the possible benefits of taking part?

The treatments in this study may lower the risk of pneumonia, and potentially reduce the risk of death. However, you may get placebo (dummy) treatment rather than the active drugs. We cannot guarantee that the study will help you. The information we get from your participation may help improve the treatment of people with stroke.

## What are the possible risks or disadvantages of being in the trial?

Treatment with any drug can be associated with side effects. The side effects associated with metoclopramide and selective oral decontamination are generally mild.

## Metoclopramide side effects:

Frequencies are defined using the following convention: ***very common*** (more than 1 in 10 people), ***common*** ( between 1 in a 100 people and 1 in 10 people), ***uncommon*** (between 1 in 1000 and 1 in a 100), ***rare*** (between 1 in 10000 and 1 in 1000), ***very rare*** (fewer than 1 in 10000), ***not known*** (cannot be estimated from the available data).

***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.

## Selective oral decontamination paste

Selective oral decontamination paste can transiently stain your gums yellow. It contains 3 antibiotics. These can affect the bacteria in your gut and cause diarrhoea. As with all medications, there is the possibility of an allergic reaction, which may be severe.

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

## What if there is a problem?

If you have a reaction to the trial medication, the trial medication will be stopped and appropriate medical care will be given. All adverse events will be monitored.

## What will happen if I don't want to carry on with the study?

If you want to stop taking the trial treatment, you can do this without withdrawing from the study and the follow-up visits. It is important for us to find out how you are doing, whether you take the trial treatment or not. It is particularly important for us to follow you up if you have experienced adverse events, or if you do not like the trial treatment. If you prefer not to be contacted personally we can get information about your health from your hospital and your GP. You are free to withdraw from all study procedures and follow-up.

## What if there is a problem?

If you have any problems or further questions about the study, at any time feel free to contact the local principapal Investigator, {insert name and contact details}

If you have a complaint about any aspect of this study or its staff and wish to complain formally, you can contact the Local Patient Advice and Liaison Service (PALS) on {insert telephone} or via email to {insert email}.

## Will my taking part in this trial be kept confidential?

Yes, all information about you will be kept confidential. Our processes are compliant with the Data protection Act 1998 and this will be overseen by the trial Sponsor (University Hospitals of North Midlands NHS Trust).

Relevant sections of your medical notes and data collected in the study may be looked at by authorised individuals at your hospital and by staff from the MAPS-2 coordinating centre. In order to contact you for follow-up, staff at the MAPS-2 coordinating centre will record your name, your NHS number, your GP, and contact

details. Your GP and other care professionals will be informed of your participation in the trial. Your records and data may also be looked at by representatives of the regulatory authorities and the study Sponsor (University Hospitals of North Midlands NHS Trust) to check that the study is being carried out correctly.

Every hospital routinely sends data to the national 'Health and Social Care Iinformation Centre', and every stroke service contributes to the 'Stroke Sentinel National Audit Programme (SSNAP)' database. If you agree to take part in this study you also agree for us to use the data your hospital sends to these organisations. We will access these databases to get information on your health status and hospital admissions. The SSNAP database records outcome for all stroke patients on admission, at discharge, and at 6 months to monitor performance of UK stroke services. If they request and you agree we may share information we have on your recovery with the SSNAP team. To do this we will use your NHS number (or equivalent), name and date of birth as identifiers.

For all other purposes personally identifiable information will be removed and replaced by an anonymous identification number. Your data will be shared anonymously with other researchers to support other ethically approved research projects and meta-analyses (this is research combining data form several studies).

## Will I receive any payments or expenses for taking part in the trial?

You will not receive payment for participating in this study. There will be no charge for the trial medication.

## What if new information becomes available?

If new information becomes available which might influence whether you continue to take part in the study, we will contact you.

## What will happen to the results of the research study?

The results of the study will be presented at scientific meetings and published in medical and scientific journals. Results will be made accessible on the MAPS-2 website at the address http://www.keele.ac.uk/maps2. The final report will also be made available to you via the local research team if requested.

## Who is organising and funding the research?

This study is being conducted by Professor Christine Roffe and the MAPS-2 collaborators. The University Hospitals of North Midlands NHS Trust is sponsoring the study. It is funded by a grant from the National Institute for Health Research, the research body for the NHS.

## Who has reviewed the study?

The study has been reviewed and approved by the North West-Greater Manchester Research Ethics Committee 17/NW/0058 the Health Research Authority and the Medicines and Healthcare Products Regulatory Authority.

## Who can I contact if I need further information?

We are happy to answer any questions you may have relating to this study. Please ask the doctors or nurses on the ward, or the local principal investigator for further information.

Thank you very much for taking the time to read this leaflet.

## The member of the research team who gave you this information:

Name:

Tel: (_____) _____

## Local principal Investigator:

Name: [insert detail]

Address: [insert detail]

Tel: (_____) _____ [insert detail]

## Chief Investigator:

Name: C. Roffe

Address: MAPS-2 Coordinating Centre, Guy Hilton Research Centre, Thornburrow Drive, Stoke-on-Trent. ST4 7QB

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