#  PARTICIPANT INFORMATION SHEET

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**Title of Study: The Metoclopramide for Avoiding Pneumonia after Stroke (MAPS-2) study**

**IRAS Project ID: 290474 ISRCTN:40512746** **CTA ref: 03057/0075/001-0001**

**Name of Chief Investigator**: Prof Christine Roffe

**Local Researcher(s**):

**Introduction**

As part of routine clinical care, research staff check if patients are eligible for research studies. You are eligible to take part in the MAPS-2 study which aims to assess whether metoclopramide can prevent pneumonia and death in patients who have had a stroke.

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 problems swallowing. The most important causes of pneumonia in stroke patients are inhalation of regurgitated or vomited stomach content.

A small study has shown that prophylactic treatment with metoclopramide, a drug which prevents vomiting and regurgitation could reduce pneumonia after stroke. While these results are promising, the study was too small to be certain that the treatment was effective.

The purpose of this study larger study is to test whether metoclopramide can prevent death and pneumonia in patients who have had a stroke.

## Why have I been invited?

You have been invited because you have had a stroke, which has affected your ability to swallow safely and we feel that you fit the requirement for this research study. You will be one of over 2,000 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.

You cannot take part in the study if any of the following apply to you:

* You already have pneumonia.
* You are allergic to metoclopramide.
* You already take anti-sickness for another medical condition on a regular basis.
* You have Parkinson’s Disease.
* You have problems with your liver.
* You have problems with your kidney.
* You are pregnant or breast-feeding.

## 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. If you are a woman of childbearing age and there may be a possibility that you are pregnant but are not sure, we would do a pregnancy test, but only with your permission.

You will then be assigned at random to the trial treatment (metoclopramide) or control (dummy treatment).

The trial treatment will be given three times a day via a feeding tube or through a vein for 2 weeks, or until discharge from hospital, if this is earlier.

## 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.

**Expenses and payments**

Participants will not be paid to participate in the study. There will be no additional travel as result of taking part in this study.

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

* For the first 2 weeks of the trial research staff will record details of your condition, your test results and your medication on a clinical log.
* After 6 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 approach the person(s) you nominated to find out whether you have changed address and how you are doing.
* 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 or similar.
* We will also contact the Office of National Statistics to find out whether you are alive 6 months after the stroke.
* You will not have any additional blood tests, X-rays or scans for this study. If you are participating in this trial, imaging data from your standard care will be shared with the study team. Typically you might have up to two CT scans of your head, as well as 2-3 chest x-rays but you would receive this imaging as part of routine care even if you did not participate in the research, so there is no additional radiation risk as a result of taking part.

## What are the possible benefits of taking part?

The treatment in this study may lower the risk of pneumonia, and potentially reduce the risk of death. However, you may get control (dummy) treatment rather than the active drugs. We cannot promise 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 are generally mild. We expect no side effects from the placebo (normal saline).

**Metoclopramide side effects:**

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.

# What happens when the research study stops?

We would like to follow your progress over six months (180 days). When all participants have been followed up, the trial results will be analysed and published in a medical journal.

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

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw we will no longer collect any information about you or from you but we will keep the information about you that we have already obtained as we are not allowed to tamper with study records and this information may have already been used in some analyses and may still be used in the final study analyses. To safeguard your rights, we will use the minimum personally-identifiable information possible.

If you were to lose capacity during the trial and were unable to decide whether you would like to continue in the trial, and an objection to your continuation was raised by your personal/professional legal representative (relative, friend or independent doctor); then you would be withdrawn from the study. If you were to be withdrawn we will no longer collect any information about you or from you but we will keep the information about you that we have already obtained. This is because we should not tamper with study records, the information may have already been used in some analyses, and may still be used in the final study analyses.

## What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers’ contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting [please provide the contact details of PALS for the local hospital]

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Nottingham but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

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

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, we will use information collected from you and your medical records during the course of the research. This information will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database at the University of Nottingham. Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (named above) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally – identifiable information possible.

You can find out more about how we use your information and to read our privacy notice at:

https://www.nottingham.ac.uk/utilities/privacy

The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

Where possible information about you which leaves the site will have your name and address removed and a unique code will be used so that you cannot be recognised from it, however sometimes we need to ensure that we can recognise you to link the research data with your medical records so in these instances we will need to know your name and date of birth. We will also need this information as we will need to follow up your medical records as part of the research, where we will need to ask the Government services that hold medical information about you (such as NHS Digital, the Office for National Statistics, among others) to provide this information to us. By signing the consent form you agree to the above.

Your personal data (address, telephone number) will be kept for 12 months after the end of the study. All research data will be kept securely for 7 years. After this time your data will be disposed of securely, unless we have permission to use it for future research projects. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team given permission by the data custodian will have access to your personal data.

In accordance with the University of Nottingham’s, the Government’s and our funders’ policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that you could not be identified) but if we need to share identifiable information we will seek your consent for this and ensure it is secure.

## 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.

# Involvement of the General Practitioner/Family doctor (GP)

If you agree, we will send a letter to your GP informing them of your participation in the trial. We also ask your permission to contact your GP or check with the NHS Information Centre to check on your condition six months after your stroke and to confirm your contact details.

# What will happen to any samples I give?

We will not be collecting samples as part of this trial.

# Will any genetic tests be done?

No.

## 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 <https://stroke.nottingham.ac.uk/maps-2>

 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 of Nottingham 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?

All research in healthcare is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. The study has been reviewed and given favourable opinion by the Research Ethics Committee Nottingham2 REC. The Health Research Authority and the Medicines and Healthcare Products Regulatory Authority have also reviewed and approved the study..

## 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:

Address:

Tel: (\_\_\_\_\_) \_\_\_\_\_\_ [insert detail]

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