***(Form to be printed on local headed paper)***

**Metoclopramide for Avoiding Pneumonia after Stroke (MAPS-2) study**

**Participant Information and Consent Form**

**(Final version 1.0: date: 08/11/2021)**

|  |  |
| --- | --- |
| ANd9GcRMW58fNpcpk6vdsxCAdA4_4C27yrMjgyXeAwmHPOS_kztWfz3HvQ | **What is this about?*** This study will test whether metoclopramide (an anti-sickness medicine) can prevent pneumonia and death in patients who have had a stroke.
 |
| ANd9GcSsQ5GaU2tdM32L5OH6CAYEQxw_geDDGCFO4st4mhRe9QW4_mW3 | **Whilst you are in hospital:*** The doctor or nurse will ask you a few questions and will test your speech, swallowing, eyesight, head, arms and legs to find out how the stroke has affected you.
* You may have a scan of your head and blood tests.
* You will be given treatment for your stroke.
* Research staff will discuss the study with you and can answer any questions you may have.
 |
| https://encrypted-tbn2.gstatic.com/images?q=tbn:ANd9GcRBl0_JbYm4XSBawoMTlunp5uPkmfa3MQRV4sMPL1qUAqcSvfw | **If you agree to take part in the study:*** If you are a woman of childbearing age and may be pregnant, with your permission we would do a pregnancy test.
* You will then be assigned at random to take either the trial treatment or a dummy treatment.
* You will be given the treatment 3 times a day for 2 weeks or until you are discharged.
 |
| ANd9GcQJdG4mPmc3Q17xRMVmW9i8srKEuCTtAvmOdUGwzrmVWW62wnbL9A | **2 weeks and 6 months after your stroke:*** For the first 2 weeks research staff will record details of your condition, your test results and what medication you are taking.

A researcher will call you after 6 months to see how you are, whether you have had any problems and how well you have recovered. |
|  | **Risks*** The side-effects are generally mild but include drowsiness, abnormal movements of the face and limbs, diarrhoea, low blood pressure and a feeling of weakness, all of which can be treated.
 |
| ANd9GcRMW58fNpcpk6vdsxCAdA4_4C27yrMjgyXeAwmHPOS_kztWfz3HvQ | **During the study:*** If you have any questions, then please ask.
* You may decide you do not want to take part anymore. This will not affect any of your care now or in the future.

All the information we hold about you will be kept in the strictest confidence. |

**Metoclopramide for Avoiding Pneumonia after Stroke (MAPS-2) study**

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

**Name of Researcher**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Name of Participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

I confirm that I have been given a copy of the Patient Information Form (Version *1.0*) and I agree:

* I will take part in the MAPS-2 study.
* I will have a pregnancy test if deemed necessary because I am of a childbearing age.
* For my medical records to be accessed.
* To be followed up for 2 weeks and at 6 months.
* For my GP to be informed of my participation and to provide information on my status before the telephone follow up.
* For my contact details to be collected and used for the purpose of the study.
* My information held by NHS digital and other UK NHS bodies may be used to help contact me or provide information about my health.

I understand that I am free to withdraw myself from the study at any point without giving a reason.

**Participant consent**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

# Name of Participant Date Signature

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Name of Person taking consent Date Signature

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_     \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Name of Independent Witness  Date         Signature

(if necessary)

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Role of Independent Witness

3 copies: 1 for participant, 1 for the project notes and 1 for the medical notes