# Does metoclopramide reduce aspiration, pneumonia and hypoxia in acute stroke patients who are fed by nasogastric tubes

Submission date 13/04/2014	<b>Recruitment status</b> No longer recruiting	<ul> <li>Prospectively registered</li> <li>Protocol</li> </ul>
<b>Registration date</b> 03/06/2014	<b>Overall study status</b> Completed	<ul> <li>[] Statistical analysis plan</li> <li>[X] Results</li> </ul>
Last Edited 08/01/2015	<b>Condition category</b> Circulatory System	Individual participant data

#### Plain English summary of protocol

#### Background and study aims

Patients who have had a stroke often lose the ability to swallow. If this happens, feeding by mouth is not safe because of the risk of choking on food and drinks. Artificial nutrition via a feeding tube often has to be given for a period of time to prevent starvation. Pneumonia is a common complication of tube feeding. One of the major causes of pneumonia in stroke patients with feeding tubes is the entry of stomach contents into the lungs (aspiration). This happens when food in the stomach is pushed back (regurgitated) into the oesophagus (gullet). This is due to a combination of delayed emptying of stomach contents into the small bowel and malfunction of the valve (oesophageal sphincter) which prevents stomach contents entering into the gullet. Metoclopramide is a drug which is commonly used in clinical practice to prevent and treat sickness and vomiting. It speeds up the passage of stomach contents into the gut and improves function of the lower oesophageal sphincter, which prevents leakage of stomach contents into the gullet. It is thought, therefore, that metoclopramide might be useful in preventing pneumonia in stroke patients with feeding tubes. Some doctors use it for this purpose, but there is no evidence form clinical studies in stroke patients to show that this is the case. The purpose of this study is to examine whether metoclopramide prevents pneumonia due to regurgitation of stomach contents in stroke patients fed via feeding tubes.

#### Who can participate?

Adult patients admitted to the Acute Stroke Unit at the University Hospital of North Staffordshire, and recruited into the study either before or within 48 hours of being fitted with a feeding tube. No more than one week must have passed since their stroke.

#### What does the study involve?

Patients that take part in the study sign a consent form and are asked questions about their health. They are also examined and some baseline information recorded. They are then given either the metoclopramide 10 mg three times a day via the feeding tube or a matching dummy treatment (placebo) for three weeks or until the feeding tube is removed. Whether they are given the metoclopramide or placebo will be chosen randomly by using a pack of sealed envelopes, prepared before the commencement of the trial. The treatment allocation is determined by chance (random) and neither the patient nor the researcher will know which of the two treatments has been given. The patient is then examined five times a week for the next 3 weeks to check for signs of pneumonia and recovery from the stroke. If they develop symptoms of a chest infection (such as cough or a high temperature) this will be reported and further investigations and treatment will be arranged in accordance with routine clinical practice. The results of any tests (for example, blood tests or chest X rays) will also be recorded in the research file. Treatment of any chest infection will be according to the hospital guidelines. The trial ends 3 weeks after the insertion of the feeding tube. On the last day of the trial the patients health, the level of recovery, and test results from their clinical notes will be reviewed and recorded.

What are the possible benefits and risks of participating?

Patients may not directly benefit from this study themselves, however their participation may help others who, in the future find themselves in the same position. There are some rare possible side effects of taking Metoclopramide. These include involuntary movements mainly affecting the muscles of the head and neck (dystonic reactions); this is reversible and causes no long term or permanent problems. Other rare effects drowsiness, diarrhoea, depression, itching, rashes and swelling of the feet.

Where is the study run from? University Hospital of North Staffordshire(UK) .

When is the study starting and how long is it expected to run for? From September 2008 to October 2011.

Who is funding the study? Keele University (UK)

Who is the main contact? Dr Auushka Warusevitane kdsampath@yahoo.co.uk

## **Contact information**

**Type(s)** Scientific

**Contact name** Dr Anushka Warusevitane

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# Additional identifiers

EudraCT/CTIS number 2006-002570-22

#### **IRAS number**

ClinicalTrials.gov number

Secondary identifying numbers N/A

# Study information

#### Scientific Title

The effect of Metoclopramide on Aspiration and Pneumonia in Stroke patients fed via nasogastric tubes

#### Acronym

MAPS Study

#### Study objectives

That regular treatment with the prokinetic agent metoclopramide prevents aspiration, pneumonia and hypoxia in stroke patients who are fed via nasogastric tubes.

**Ethics approval required** Old ethics approval format

**Ethics approval(s)** North Staffordshire Local Research Ethics Committee; 30/07/2008, ref. 07/Q2604/41

**Study design** Double-blind randomised controlled trial done on single site

**Primary study design** Interventional

**Secondary study design** Randomised controlled trial

**Study setting(s)** Hospital

**Study type(s)** Prevention

#### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

#### Health condition(s) or problem(s) studied

Cerebrovascular disease (acute strokes) and Pneumonia

#### Interventions

Patients were randomized to one of two groups:

1) The intervention group: colourless metoclopramide syrup 10 mg tds (three times a day) (08: 00, 15:00, and 21:00) via the nasogastric tube for 3 weeks or until discontinuation of nasogastric feeding

2) The control group: normal saline 10 ml via nasogastric tube tds (three times a day) (08:00, 15: 00, and 21:00) for 3 weeks or until discontinuation of nasogastric feeding

#### Intervention Type

Drug

**Phase** Not Applicable

#### Drug/device/biological/vaccine name(s)

Metoclopramide

#### Primary outcome measure

The number of diagnosed episodes of pneumonia (any)

Patients were examined clinically daily for signs and symptoms of pneumonia. Also a daily review of patients case note was done. If there was a clinical suspicion of pneumonia haematological (White cell count -WBC) and biochemical (CRP) investigations and a chest radiograph was requested. Laboratory test results and chest radiographs were reviewed (on the same day of request) for the diagnosis of pneumonia.

The fulfilment all these criteria, namely, the presence of abnormal chest signs and symptoms on clinical examination, elevation of WBC and CRP levels and development of new infiltrates in chest radiograph were required to diagnose pneumonia. (British Thoracic Society recommendations for the diagnosis of pneumonia in a hospital)

#### Secondary outcome measures

1. The number of episodes of witnessed aspiration - Daily review of patients case notes and nurses observation charts was done to identify documented episodes of aspiration. This continued daily over 21 days from recruitment or until the NG tube was removed which ever was earlier

2. The number of antibiotic days- Daily review of patients prescription charts to review of antibiotic prescriptions - continued daily over 21 days from recruitment or until the NG tube was removed which ever was earlier

3. The number of different antibiotics prescribed Daily review of patients prescription chartscontinued over 21 days from recruitment or until the NG tube was removed which ever was earlier

4. The highest white blood count Daily review of patients investigation results from hospital online patients laboratory results system and review of patients case-note - continued over 21 days from recruitment or until the NG tube was removed which ever was earlier

5. The highest CRP level Daily review of patients investigation results from hospital online patients laboratory results section and case-note review- continued over 21 days from recruitment or until the NG tube was removed which ever was earlier

6. End of trial outcomes (Nasogastric tube was removed as swallowing improved, referred for a PEG tube insertion and nasogastric tube removed due to withdrawal of treatment/palliation or commencement of the Liverpool care pathway for the dying.) Daily patient case notes review, continued over 21 days from recruitment or until the NG tube was removed which ever was

earlier

7. The lowest oxygen saturation Daily review of patients case-notes and nurses observation charts. Also, daily measurement of oxygen saturations (using a pulse oximeter) at 10 am for 10 minutes and recording the lowest oxygen saturation recorded during that time. Continued daily over 21 days from recruitment or until the NG tube was removed which ever was earlier

#### Overall study start date

01/09/2008

#### **Completion date**

01/10/2011

# Eligibility

#### Key inclusion criteria

All adult patients admitted to the Acute Stroke Unit at University Hospital of North Staffordshire were considered for enrolment into the study if they required placement of a nasogastric tube for enteral feeding and if they could be recruited either before or within 48 hours of insertion of the nasogastric tube, no longer than a week had passed since the stroke.

#### Participant type(s)

Patient

**Age group** Adult

**Sex** Both

Target number of participants

60 acute stroke patients

#### Key exclusion criteria

- 1. Patients who had a nasogastric tube in place for more than two days
- 2. More than seven days following the stroke
- 3. Patients with signs and symptoms of a chest infection before recruitment

4. Patients with a known oesophageal stricture or a carcinoma which would interfere with the insertion of a nasogastric tube

- 5. Patients with terminal illnesses such as advanced malignancies
- 6. Patients on concurrent dopaminergic drugs

7. Patients with a history of neurodegenerative condition which should affect swallowing e.g. Parkinsons disease and motor neurone disease

8. Patients who had presented as strokes, but later were diagnosed to have a non stroke pathology (e.g. brain tumour) were excluded retrospectively

9. Pregnancy

10. Patients recruited to another study

11. Patients where a decision not to treat actively had been made either due to poor chances of survival due to severity of the stroke or because of the patients prior expressed wishes

12. Known contraindications for the use of metoclopramide: Gastro-intestinal obstruction, perforation or haemorrhage; 3-4 days after gastro-intestinal surgery; phaeochromocytoma; breast-feeding

Date of first enrolment 01/09/2008

Date of final enrolment 01/10/2011

## Locations

**Countries of recruitment** England

United Kingdom

**Study participating centre Acute Stroke Unit (ward 232)** Stoke-on-Trent United Kingdom ST4 6QG

## Sponsor information

**Organisation** Keele University (UK)

**Sponsor details** Institute for Science and Technology Staffordshire Stoke-on-Trent England United Kingdom ST5 5BG

**Sponsor type** University/education

ROR https://ror.org/00340yn33

# Funder(s)

**Funder type** University/education

**Funder Name** Keele University (UK)

### **Results and Publications**

**Publication and dissemination plan** Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not provided at time of registration

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2015		Yes	No