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

Submission date
13/04/2014

Recruitment status
No longer recruiting

Registration date
03/06/2014

Overall study status
Completed

Last Edited
08/01/2015

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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Contact information

Type(s)
Scientific

Contact name
Dr Anushka Warusevitane

Contact details
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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 charts- continued 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
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Sponsor information

Organisation
Keele University (UK)

Sponsor details
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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