

# Randomisation

Participant ID

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(REDCap auto generated )

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ISRCTN 40512746

## Metoclopramide for Avoiding Pneumonia after Stroke Trial

### Baseline and randomisation form v1.5

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#### Section A: Participant identifiers

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A1. Centre name:

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A2. Participant ID

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(Participant ID - REDCap auto generated)

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A3. Participant Initials

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(3 uppercase letters or 2 separated by a hyphen (-))

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A4. Date of birth

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(dd-mm-yyyy ([age\_today\_r]))

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#### Section B: Inclusion/exclusion criteria and consent

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##### **Inclusion criteria (B1-B3 must be YES and either B4 or B5 must be YES).**

B1. Adults (18 years and over)

 Yes  No

B2. Clinical diagnosis of acute stroke

 Yes  No

B3. Within 24 hours of symptom onset

 Yes  No

(in wake-up stroke the onset is defined as the time the patient awoke or was found)

B4. Moderate to severe neurological impairment (NIHSS Score  $\geq$  10) Yes  No

B5. NIHSS  $\geq 6$  AND Dysphagia, e.g. unable to take normal unmodified oral diet or fluids because:  Yes  No

- a. Too drowsy to be assessed formally, or
- b. failed bedside assessment of swallowing

### Exclusion criteria

B6. Definite or probable pneumonia  Yes  No

- a. abnormal CXR suggestive of pneumonia, or
- b. focal chest signs with fever  $\geq 38^{\circ}\text{C}$ , or
- c. receiving antibiotic treatment at time of presentation

B7. Contraindications to metoclopramide  Yes  No

- a. hypersensitivity to metoclopramide
- b. epilepsy
- c. gastrointestinal obstruction, perforation, or haemorrhage
- d. gastrointestinal surgery within the last week
- e. Parkinson's disease
- f. treatment with levodopa or dopaminergic agonists
- g. pheochromocytoma
- h. history of neuroleptic malignant syndrome
- i. history of metoclopramide-induced tardive dyskinesia
- j. known history of methaemoglobinaemia with metoclopramide or of NADH cytochrome -b5 deficiency

B8. Clinical indication for regular antiemetic treatment  Yes  No

B9. Known cirrhosis of the liver  Yes  No

B10. Known severe renal dysfunction (eGFR < 30 ml/min)  Yes  No

B11. Pregnant or breast feeding  Yes  No

B12. Moribund (expected to die within the next 48 hours)  Yes  No

B13. Co-morbid conditions with life expectancy < 3 months  Yes  No

B14. Inability to gain consent (patient or legal representative) or consent declined  Yes  No

B15. Taking part in another CTIMP, device or interventional trial which is not sponsored by the University of Nottingham during the trial and follow-up period  Yes  No

Exclusion criteria B6-B15 must be "No" to proceed.

**Consent**

B16. Has appropriate consent been obtained?  Yes  No

B17. If yes, please specify who gave consent

Participant

Personal legal representative (family member)

Personal Legal representative (friend)

Independent physician

Professional legal representative

**Section C: Clinical details**

C1. Date and time of onset of symptoms  
(in wake-up stroke the onset is defined as the time the patient awoke or was found unless this is more than 12 h from last known well)

\_\_\_\_\_

(dd-mm-yyyy hh:mm (24hr))

C2. Date and time of presentation at hospital

\_\_\_\_\_

(dd-mm-yyyy hh:mm (24hr))

C3. Age  
(Age will be calculated automatically and fixed at randomisation)

\_\_\_\_\_

(years)

C4. Sex  Male  Female

C5. Usual place of abode

Home alone

Home with others

Care home

Other institution

Other

C6. Modified Rankin Scale (pre-stroke)  
view detail

0- No symptoms at all

1- No significant disability despite symptoms

2- Slight disability

3- Moderate disability

4- Moderately severe disability

5- Severe disability

C7. Clinical Frailty Scale  
view detail

1. Very fit Robust, active, energetic, well-motivated and fit; these people commonly exercise regularly and are in the most fit group for their age
2. Well People who have no active disease symptoms but are less fit than category 1. Often, they exercise or are very active occasionally, e.g. seasonally
3. Managing well People whose medical problems are well controlled, but are not regularly active beyond routine walking
4. Vulnerable While not dependent on others for help, symptoms limit activities . A common complaint is being "slowed up", and/or being tired during the day
5. Mildly frail These people often have more evident slowing, and need help in high order instrumental activities of daily living (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and housework
6. Moderately frail People need help with all outside activities and with keeping house. Inside, they often have problems with stairs and need help with bathing and might need minimal assistance (cueing, stand by) with dressing
7. Severely frail Completely dependent for personal care, from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~ 6 months)
8. Very severely frail Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness
9. Terminally ill Approaching the end of life. This category applies to people with a life expectancy < 6 months, who are not otherwise evidently frail

With a CFS greater than 7, participant is likely approaching the end of life and may not meet the inclusion and exclusion criteria (B13).

C8. Comorbid conditions and treatments:

C8a. Heart failure  Yes  No

C8b. Ischaemic heart disease  Yes  No

C8c. Chronic obstructive airways disease or asthma  Yes  No

C8d. Other chronic lung problems  Yes  No

C8e. Diabetes mellitus  Yes  No

C8f. Prior stroke  Yes  No

C8g. Wears dentures  Yes  No

C9. Antiemetic treatment since the stroke  Yes  No

C10. Body temperature (°C)

(Permitted range 33.0-41.0 (normal 34.9-39.9))

C11. Oxygen saturation on air (%)

(Permitted range 80-100%)

C12. Heart rate (beats/minute)

(Permitted range 19-250 bpm)

### Section D: NIHSS

D1a. Level of Consciousness (LOC)

- 0 = Alert; keenly responsive
- 1 = Not alert; but arousable by minor stimulation to obey, answer, or respond
- 2 = Not alert; requires repeated stimulation to attend, or is obtunded and requires strong or painful stimulation to make movements (not stereotyped)
- 3 = Responds only with reflex motor or autonomic effects or totally unresponsive, flaccid, and areflexic

D1b. LOC Questions

- 0 = Answers both questions correctly
- 1 = Answers one question correctly; or intubated or severe dysarthria or language barrier
- 2 = Answers neither question correctly; or coma

Patient is asked to state the month & his/her age

D1c. LOC Commands

- 0 = Performs both tasks correctly
- 1 = Performs one task correctly
- 2 = Performs neither task correctly

The patient is asked to open and close the eyes and then to grip and release the non-paretic hand

## D2. Best Gaze

If a patient has an isolated peripheral nerve palsy score 1.

- 0 = Normal
- 1 = Partial gaze palsy; gaze is abnormal in one or both eyes, but forced deviation or total gaze paresis is not present
- 2 = Forced deviation, or total gaze paresis not overcome by the oculoccephalic manoeuvre

## D3. Visual Fields

- 0 = No visual loss
- 1 = Partial hemianopia
- 2 = Complete hemianopia; or extinction in D11
- 3 = Bilateral hemianopia (blind including cortical blindness)

## D4. Facial Palsy

- 0 = Normal symmetrical movements
- 1 = Minor paralysis (flattened nasolabial fold, asymmetry on smiling)
- 2 = Partial paralysis (total or near-total paralysis of lower face)
- 3 = Complete paralysis of one or both sides (absence of facial movement in the upper and lower face)

## D5a. Motor Arm (LEFT)

- 0 = No drift; limb holds 90 (or 45) degrees for full 10 seconds
- 1 = Drift; limb holds 90 (or 45) degrees, but drifts down before full 10 seconds; does not hit bed or other support
- 2 = Some effort against gravity; limb cannot get to or maintain (if cued) 90 (or 45) degrees, drifts down to bed, but has some effort against gravity
- 3 = No effort against gravity; limb falls
- 4 = No movement

## D5b. Motor Arm (RIGHT)

- 0 = No drift; limb holds 90 (or 45) degrees for full 10 seconds
- 1 = Drift; limb holds 90 (or 45) degrees, but drifts down before full 10 seconds; does not hit bed or other support
- 2 = Some effort against gravity; limb cannot get to or maintain (if cued) 90 (or 45) degrees, drifts down to bed, but has some effort against gravity
- 3 = No effort against gravity; limb falls
- 4 = No movement

## D6a. Motor Leg (LEFT)

- 0 = No drift; leg holds 30-degree position for full 5 seconds
- 1 = Drift; leg falls by the end of the 5-second period but does not hit bed
- 2 = Some effort against gravity; leg falls to bed by 5 seconds, but has some effort against gravity
- 3 = No effort against gravity; leg falls to bed immediately
- 4 = No movement

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D6b. Motor Leg (RIGHT)

- 0 = No drift; leg holds 30-degree position for full 5 seconds
  - 1 = Drift; leg falls by the end of the 5-second period but does not hit bed
  - 2 = Some effort against gravity; leg falls to bed by 5 seconds, but has some effort against gravity
  - 3 = No effort against gravity; leg falls to bed immediately
  - 4 = No movement
- 

D7. Limb Ataxia

- 0 - Absent; or coma or limb paralysed or patient does not understand
  - 1 - Present in one limb
  - 2 - Present in two limbs
- 

D8. Sensory

- 0 = Normal; no sensory loss
  - 1 = Mild-to-moderate sensory loss; patient feels pinprick is less sharp or is dull on the affected side; or there is a loss of superficial pain with pinprick, but patient is aware of being touched
  - 2 = Severe to total sensory loss; patient is not aware of being touched in the face, arm, and leg; or coma
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D9. Best Language

- 0 = No aphasia; normal
  - 1 = Mild-to-moderate aphasia; some obvious loss of fluency or facility of comprehension, without significant limitation on ideas expressed or form of expression. Reduction of speech and/or comprehension, however, makes conversation about provided materials difficult or impossible. For example, in conversation about provided materials, examiner can identify picture or naming card content from patient's response
  - 2 = Severe aphasia; all communication is through fragmentary expression; great need for inference, questioning, and guessing by the listener. Range of information that can be exchanged is limited; listener carries burden of communication. Examiner cannot identify materials provided from patient response
  - 3 = Mute, global aphasia; no usable speech or auditory comprehension; or coma
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D10. Dysarthria

- 0 = Normal
  - 1 = Mild-to-moderate dysarthria; patient slurs at least some words and, at worst, can be understood with some difficulty
  - 2 = Severe dysarthria; patient's speech is so slurred as to be unintelligible in the absence of or out of proportion to any dysphasia, or is mute/anarthric
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D11. Extinction and Inattention (formerly Neglect):

- 0 = No abnormality; or coma
- 1 = Visual, tactile, auditory, spatial, or personal inattention or extinction to bilateral simultaneous stimulation in one of the sensory modalities
- 2 = Profound hemi-inattention or extinction to more than one modality; does not recognise own hand or orients to only one side of space

**Section E: Glasgow Coma Scale (GCS)**

E1. Eye opening

- 4 - Spontaneous  
 3 - To sound  
 2 - To pressure  
 1 - None (including anaesthetised and ventilated patients)

E2. Verbal response

- 5 - Orientated  
 4 - Confused  
 3 - Words  
 2 - Sounds  
 1 - None (including anaesthetised and ventilated patients)

E3. BEST Motor response

- 6 - Obeys commands  
 5 - Localising  
 4 - Normal flexion  
 3 - Abnormal flexion  
 2 - Extension  
 1 - None (including anaesthetized and ventilated patients)

**Section F: Randomisation**

F1. Weight (kg)

A weight below 40kgs can indicate a severe underlying illness limiting life expectancy to less than 3 months, which is an exclusion criteria (B13).

\_\_\_\_\_ (Permitted range 35-200 kg)

F2. Date/time of randomisation

\_\_\_\_\_ (The date/time will be filled-in automatically after randomisation)

F3. Centre repatriate percentage

\_\_\_\_\_ (Repatriate percentage will be updated automatically after randomisation)

F4a. Associate PI involved?

Yes  No  Not applicable

F4b. Name of associate PI

\_\_\_\_\_ (Associate PI)

**Comments**

Comments