

Randomisation

Participant ID

(REDCap auto generated)



Metoclopramide for Avoiding Pneumonia after Stroke Trial

Baseline and randomisation form v1.7

Section A: Participant identifiers

A1. Centre name:

A2. Participant ID

(Participant ID - REDCap auto generated)

A3. Participant Initials

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

A4. Date of birth

(dd-mm-yyyy ([age_today_r]))

Section B: Inclusion/exclusion criteria and consent

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 ≥ 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

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

- ☐ 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

D1c. LOC Commands

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

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

D2. Best Gaze

If a patient has an isolated peripheral nerve paresis 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 oculocephalic 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

D6b. Motor Leg (RIGHT)	<input type="radio"/> 0 = No drift; leg holds 30-degree position for full 5 seconds <input type="radio"/> 1 = Drift; leg falls by the end of the 5-second period but does not hit bed <input type="radio"/> 2 = Some effort against gravity; leg falls to bed by 5 seconds, but has some effort against gravity <input type="radio"/> 3 = No effort against gravity; leg falls to bed immediately <input type="radio"/> 4 = No movement
D7. Limb Ataxia	<input type="radio"/> 0 - Absent; or coma or limb paralysed or patient does not understand <input type="radio"/> 1 - Present in one limb <input type="radio"/> 2 - Present in two limbs
D8. Sensory	<input type="radio"/> 0 = Normal; no sensory loss <input type="radio"/> 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 <input type="radio"/> 2 = Severe to total sensory loss; patient is not aware of being touched in the face, arm, and leg; or coma
D9. Best Language	<input type="radio"/> 0 = No aphasia; normal <input type="radio"/> 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 <input type="radio"/> 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 <input type="radio"/> 3 = Mute, global aphasia; no usable speech or auditory comprehension; or coma
D10. Dysarthria	<input type="radio"/> 0 = Normal <input type="radio"/> 1 = Mild-to-moderate dysarthria; patient slurs at least some words and, at worst, can be understood with some difficulty <input type="radio"/> 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
D11. Extinction and Inattention (formerly Neglect):	<input type="radio"/> 0 = No abnormality; or coma <input type="radio"/> 1 = Visual, tactile, auditory, spatial, or personal inattention or extinction to bilateral simultaneous stimulation in one of the sensory modalities <input type="radio"/> 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 35.00-200.00 kg - please note format: 2 decimal places only)

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)

Section G: Investigator

G1. Name of person completing the form

G2. Email of person completing the form

(Email to notify)

PI and associate PI details

G4. Please enter PI name

(PI Name)

G5. Email of PI

(PI Email to notify)

G6a. Associate PI involved?

☐ Yes ☐ No ☐ Not applicable

G6b. Name of associate PI

(Associate PI)

Comments

Comments