

Day 14 Followup

Participant ID

(REDCap auto generated)



ISRCTN 40512746

Metoclopramide for Avoiding Pneumonia after Stroke Trial

Day 14 or Discharge Day assessment v2.4

Section A: Participant details

A1. Participant ID :

A2. Participant initials :

A3. Participant status

If deceased complete the "Notification of death" CRF.

If withdrawn complete the "Withdrawal" CRF.

If discharged complete the "Discharged to the community" CRF.

- Alive and in hospital
 Discharged prior to day 14
 Withdrawn & refused any follow-up
 Palliative care
 Deceased

A4. Date of data collection

(dd-mm-yyyy (day [day_calculated_d14]))

Section B: Clinical details

B1. Thrombolysis

 Yes No

B2. Mechanical thrombectomy

 Yes No

B3. Decompressive hemicraniectomy

 Yes No

B4. OCSF syndrome

- TAC
 PAC
 LAC
 POC
 Not a stroke

B5a. CTMRI diagnosis

- Acute ischaemia or infarction
 Intracerebral haemorrhage
 No acute ischaemia/infarction or haemorrhage
 Other
 (If other, please provide details)

B5b. If other CTMRI diagnosis, please give details

(CTMRI diagnosis)

B6. Final (combined clinical and CT) diagnosis.

A participant with clinical signs of a stroke and normal CT or a CT with non-specific changes will be defined as a cerebral infarct

- Cerebral infarct
 Intracerebral haemorrhage
 Subdural haemorrhage
 Subarachnoid haemorrhage
 Transient ischaemic attack
 Not a stroke

B7a. Did the participant receive any other antiemetics during the trial period?

- Yes
 No

B7b. If yes, how many times did the participant receive any other antiemetics during the trial period?

B7c. If yes, which antiemetic did the participant receive during the trial period?

Section C: Adverse events

C1a. A further stroke

- Yes No
 (If yes, please complete SAE/ EoSI form and categorise as EoSI)

C1b. If yes, please specify the date of the stroke

(dd-mm-yyyy)

C1c. If yes, please specify the stroke type

- Infarct
 Haemorrhage
 No imaging diagnosis

C2a. A collapse or cardiac / respiratory arrest requiring resuscitation

- Yes No
 (If yes, please complete SAE/ EoSI form and categorise as EoSI)

C2b. If yes, please specify the date of the collapse

(dd-mm-yyyy)

C3a. Severe bradycardia requiring atropine or pacemaker insertion
If 'yes' please complete a Serious Adverse Events form.

- Yes No
 (If yes, please complete SAE.)

C3b. If yes, please specify the date of the bradycardia

(dd-mm-yyyy)

C4a. Definite epileptic seizure (focal or generalised)

Yes No
(If yes, please complete SAE/ EoSI form and categorise as EoSI)

C4b. If yes, please specify the date of the seizure

(dd-mm-yyyy)

C5a. Orofacial dyskinesia

Yes No
(If yes, please complete SAE/ EoSI form and categorise as EoSI)

C5b. If yes, please specify the date the orofacial dyskinesia

(dd-mm-yyyy)

C6a. Tardive dyskinesia

Yes No
(If yes, please complete SAE/ EoSI form and categorise as EoSI)

C6b. If yes, please specify the date of the tardive dyskinesia

(dd-mm-yyyy)

C7a. A NEW diagnosis of Parkinson's disease

Yes No
(If yes, please complete SAE/ EoSI form and categorise as EoSI)

C7b. If yes, please specify the date of diagnosis

(dd-mm-yyyy)

C8. Any serious adverse event that is NOT a known complication of stroke or known side effect of Metoclopramide

Yes No
(If yes, please complete SAE.)

C9. Please list any non-serious adverse event that happen from day participant randomised until day 14.

For each non-serious adverse event, please at least give information about when event began and event diagnosis.

If there have been any SAEs, please complete the SAE report form.

Remember that complications of the stroke (Appendix 3) and known side effects of Metoclopramide (Appendix 1) should not be reported as SAEs

Section D: NIHSS

D1. Was NIHSS performed within +/- 3 days of day-14 or date of discharge to the community? Yes
 No

Specify reason if not discharged, withdrawn or died

If NIHSS was not performed:

D1a. If NIHSS not performed, please specify reason why

 (Reason NIHSS not performed)

D1b. If NIHSS performed prior to day-14/day of discharge, enter date

 (Date NIHSS performed dd-mm-yyyy)

D1c. If full NIHSS break down is not available please give total NIHSS here.

35: Unconscious/ Intubated
 42: Dead
 NA: no NIHSS after 72 hours

 (NIHSS total score: 35:Unconscious/ Intubated
 42:Dead or not done)

NIHSS break down:

D2a. 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

D2b. 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

D2c. 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

D3. Best Gaze

Only horizontal eye movements will be tested. If a patient has an isolated peripheral nerve paresis (CN III, IV or VI), 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

D4. Visual Fields

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

D5. 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)
-

D6a. 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
-

D6b. 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
-

D7a. 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
-

D7b. 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
-

D8. Limb Ataxia

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

D9. 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

D10. 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

D11. 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

D12. 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

D13. NIHSS total

35: Unconscious/ Intubated
 42: Dead or NIHSS not performed
 NA: no NIHSS after 72 hours

(Calculated)

Section E: Modified Rankin Scale

E1. Modified Rankin Scale
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
- 6- Died
- ND- Not done

E2. MRS total

6: Dead, withdrawn or unknown

(Calculated)

Section F: Dysphagia Severity Rating Scale (DSRS)

F1. Was DSRS performed on day-14 or day of discharge?

- Yes
- No

Specify reason if not discharged, withdrawn or died

F1a. If DSRS not performed, please specify reason why

(Reason DSRS not performed)

F2. Ability to drink fluids

- 0 = Normal fluids
- 1 = Syrup consistency
- 2 = Custard consistency
- 3 = Pudding consistency
- 4 = No oral fluids

F3. Ability to eat foods

- 0 = Normal food
- 1 = Selected textures
- 2 = Soft, moist diet
- 3 = Puree
- 4 = No oral feeding

F4. Supervision and help needed during meals

- 0 = I am eating independently
- 1 = I need supervision when I eat
- 2 = I need to be fed by another person
- 3 = Only a swallowing therapist can feed me
- 4 = I cannot take any foods by mouth

F5. DSRS total

0: Dead or DSRS not performed

(Calculated)

Section G: EuroQol 5D-5L

G1. Was EuroQol 5D-5L performed on day-14 or day of discharge?

- Yes
 No

Specify reason if not discharged, withdrawn or died

G1a. If EQ-5D-5L not performed, please specify reason why

(Reason EQ-5D-5L not performed)

G2. MOBILITY
Please click the ONE box that best describes your health TODAY.

- I have no problems in walking about
 I have slight problems in walking about
 I have moderate problems in walking about
 I have severe problems in walking about
 I am unable to walk about

G3. SELF-CARE
Please click the ONE box that best describes your health TODAY.

- I have no problems washing or dressing myself
 I have slight problems washing or dressing myself
 I have moderate problems washing or dressing myself
 I have severe problems washing or dressing myself
 I am unable to wash or dress myself

G4. USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)
Please click the ONE box that best describes your health TODAY.

- I have no problems doing my usual activities
 I have slight problems doing my usual activities
 I have moderate problems doing my usual activities
 I have severe problems doing my usual activities
 I am unable to do my usual activities

G5. PAIN / DISCOMFORT
Please click the ONE box that best describes your health TODAY.

- I have no pain or discomfort
 I have slight pain or discomfort
 I have moderate pain or discomfort
 I have severe pain or discomfort
 I have extreme pain or discomfort

G6. ANXIETY / DEPRESSION
Please click the ONE box that best describes your health TODAY.

- I am not anxious or depressed
 I am slightly anxious or depressed
 I am moderately anxious or depressed
 I am severely anxious or depressed
 I am extremely anxious or depressed

G7. EQ-5D-5L total

25: Dead or EQ-5D-5L not performed

(Calculated)

Health score

G8. Tell us about your health

We would like to know how good or bad your health is TODAY.

This scale is numbered from 0 to 100.

100 means the best health you can imagine.
0 means the worst health you can imagine.

Please click on the scale to indicate how your health is TODAY.

0 - The worst health you can imagine or death 50 100 - The best health you can imagine



(Place a mark on the scale above)

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Section H: Transferred or discharged

H1. Transferred to another hospital? Yes No
If yes, please complete Transfer form.

H2. Discharged into the community? Yes No
If yes, please complete the Discharge form

Section I: Coenrolment

I1. Please list any other trials into which the participant was coenrolled (giving acronyms where applicable)

Section J: Pneumonia diagnosed

J1. Diagnosis of pneumonia made at any time during day 1-14 No pneumonia
 Pneumonia diagnosed
 Pneumonia mis-diagnosed
(If mis-diagnosed, please provide details)

J1a. If changed, please give details

*If pneumonia mis-diagnosed then please update Pneumonia diagnosis CRF

Comments and full explanation for missing data

Are any values missing due to tests not done (or measures not taken), or because data are unknown and every effort has been made to find the data - i.e. 'Not done' / 'Not known'? Yes
 No

Comments

If any values are missing, please provide a full explanation
