Serious Adverse Event

Participant ID

_____
(REDCap auto generated)

MAPS-2
ISRCTN 40512746

Metoclopramide for Avoiding Pneumonia after Stroke Trial

Serious Adverse Event or Event of Special Interest v1.7

Events which are NOT considered AEs and do NOT require reporting:

1. Medical or surgical procedure (e.g., surgery, endoscopy, tooth extraction, transfusion); but the condition that led to the procedure is an AE.
2. Pre-existing disease or conditions present or detected at the start of the study that did not worsen.
3. Situations where an untoward medical occurrence has not occurred (e.g., hospitalisations for cosmetic elective surgery, social and/or convenience admissions).
4. Overdose of concurrent medication without any signs or symptoms.
5. Disease or disorder being studied (stroke) or sign or symptom associated with the disease or disorder unless more severe than expected for the participant's condition. A list of symptoms, signs, and complications associated with stroke (Appendix 3).

References:

Appendix 1: Side-effects of metoclopramide (based on the Hameln Pharma Ltd SmPC)
Appendix 3: Expected Stroke Symptoms and Complications to be recorded in patient notes but not subject to expedited reporting

Specific safety endpoints - Events referred to as Events of Special Interest (EoSI):
- Stroke Recurrence
- Cardiorespiratory arrest requiring resuscitation
- Severe bradycardia requiring atropine or pacemaker insertion
- Definite epileptic seizure (focal or general)
- Oculogyric crises
- Tardive dyskinesia
- A new diagnosis of Parkinson's disease

Section A: Participant details

A1. Centre name :

A2. Participant ID :

A3. Participant initials :

Section B: Event Information

B1. Report status	◯ Initial report ◯ Follow-up
B2. Date and time event began	_____ (dd-mm-yyyy (day [day_calculated_s]))
B3. Date and time of investigator awareness	_____
B4. Date and time of report	_____ ([calc_time_to_report_hm_s] hours after awareness)
B5. When did this event happen with regard to the treatment?	◯ Before ◯ During ◯ After
B6. Please describe the event, e.g. stroke recurrence, epileptic seizure, fracture, chest pain, new limb weakness. Note: Death is an end result, not an independent event	_____
B6a. Event diagnosis Please select the categories of the event.	_____
B6b. If other, please state the medical condition (diagnosis, not treatment)	_____
B7a. Nature of event	◯ Single episode ◯ Multiple episodes
B7b. Intensity of event	◯ Mild ◯ Moderate ◯ Severe

Did any of the following events occur?

B8a. If the participant has died, was this event the primary cause of death?	◯ Yes ◯ No (If yes, please provide details)
B8b. If yes, please enter date of death	_____
B9. Life threatening	◯ Yes ◯ No
B10a. Hospitalisation or hospitalisation prolonged	◯ Yes ◯ No (If yes, please provide details)
B10b. If hospitalised, start date of hospitalisation	_____
B10c. If hospitalised, end date of hospitalisation	_____
B11. Persistent or significant disability/incapacity	◯ Yes ◯ No

B12. Congenital anomaly / birth defect	◯ Yes ◯ No
B13. Medically important	◯ Yes ◯ No
B14. Relationship to study drug	◯ Not related ◯ Improbable ◯ Possible ◯ Probable ◯ Definite
B15. Please classify the event	◯ SAE ◯ SAR ◯ SUSAR ◯ EoSI
B16. Causality - detail possible suspected causes	_____
B17a. Action taken regarding study drug	◯ Continued ◯ Dose interrupted ◯ Discontinued (If discontinued or interrupted, please provide details)
B17b. If discontinued or interrupted, please specify the date/time of dose interruption or discontinuation	_____
B18a. Clinical outcome of this event	◯ Resolved ◯ Recovered with sequelae ◯ Event ongoing ◯ Died (If ongoing or recovered, please provide details)
B18b. If 'Event ongoing' or 'Recovered with sequelae', please provide details	_____

Section C: Relevant results of tests and diagnostic procedures Diagnostic evidence

1a. Test/Procedure	_____ (C1 Test/ Procedure)
1b. Test date	_____ (C1 Date DD-MM-YYYY)
1c. Test result	_____ (C1 Test result)
2a. Test/Procedure	_____ (C2 Test/ Procedure)

2b. Test date

(C2 Date DD-MM-YYYY)

2c. Test result

(C2 Test result)

3a. Test/Procedure

(C3 Test/ Procedure)

3b. Test date

(C3 Date DD-MM-YYYY)

3c. Test result

(C3 Test result)

4a. Test/Procedure

(C4 Test/ Procedure)

4b. Test date

(C4 Date DD-MM-YYYY)

4c. Test result

(C4 Test result)

Section D: Relevant past medical history

D1a. Any relevant past medical history? ◯ Yes ◯ No
(If yes, please provide details)

D1b. If yes, please give detail

Section E: Relevant concomitant medication

E1a. Any relevant concomitant medication? ◯ Yes ◯ No
(If yes, please provide details)

E1b. If yes, please give detail

Section F: Investigator

F1. Investigator's detailed description of the event

F2. Name of person completing the form

_____

F3. Email of person completing the form

_____
(Email to notify and send review to)

Please send email immediately but no later than 24 hours after awareness to the event

Section G: PI review

G1. Reviewed by PI

◯ Reviewed
◯ Awaiting review

G2a. I have reviewed and agree with this classification

◯ Agreed
◯ Disagree
◯ Outstanding information

G2b. PI Comments

Please give more information if "Disagree" or "Outstanding information"

G3. Please enter PI name

_____

G4. Email of PI

_____
(PI Email to notify and send CI review to)

G5b. Please sign the form

_____
(✍ Signature)

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APPENDIX 1: Side-effects of metoclopramide (based on the Hameln Pharma Ltd SmPC)

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General side-effects, Common (1 in 100 to 1 in 10) or very common (> than 1 in 10)
Asthenia
Depression
Diarrhoea
Drowsiness
Hypotension
Menstrual cycle irregularities
Movement disorders
Parkinsonism

Uncommon (1 in 1,000 to 1 in 100)
Arrhythmias
Hallucination
Hyperprolactinaemia
Level of consciousness decreased

Rare 1 in 10,000 to 1 in 1,000) or very rare (less than 1 in 10,000)
Confusion
Galactorrhoea
Seizure
Frequency not known
Atrioventricular block
Blood disorders
Cardiac arrest
Gynaecomastia
Hypertension
Neuroleptic malignant syndrome
QT interval prolongation
Shock
Syncope
Tremor

Specific side-effects, frequency not known with parenteral use
Anxiety
Dizziness
Dyspnoea
Oedema
Skin reactions
Visual impairment

Side-effects, further information
Metoclopramide can induce acute dystonic reactions involving facial and skeletal muscle spasms and oculogyric crises. These dystonic effects are more common in the young (especially girls and young women) and the very old; they usually occur shortly after starting treatment with metoclopramide and subside within 24 hours of stopping it. Injection of an antiparkinsonian drug such as procyclidine will abort dystonic attacks.

APPENDIX 3: Expected Stroke Symptoms and Complications to be recorded in patient notes but not subject to expedited reporting

APPENDIX 3: Expected Stroke Symptoms and Complications

These events are not subject to expedited reporting.
• Pneumonia: complete the Pneumonia Diagnosis form
• Death due to the presenting stroke or its complications: complete a Notification of Death form.

All other expected stroke symptoms and complications to be recorded in patient notes..
These events are aspects of the original qualifying disease and do not constitute adverse events.
• Stroke symptoms (reduced level of consciousness, confusion, hemianopia, double vision, facial paresis, other cranial nerve palsies, hemiparesis, hemi sensory loss, ataxia, incoordination, speech problems, dysarthria, hemi inattention, dysphagia
• Extension of the initial stroke
• Haemorrhagic transformation of the stroke
• Malignant cerebral oedema
• Venous thromboembolism
• Atrial fibrillation
• Carotid artery stenosis
• Decubitus ulcer
• Shoulder pain
• Other musculoskeletal pains
• Urinary incontinence
• Urinary retention
• Dehydration
• Renal impairment
• Hypertension (unless it is very severe and has only started after randomization)
• Dyslipidaemia
• Headaches
• Confusion
• Delirium
• Falls
• Fractures
• Elective and diagnostic procedures (carotid endarterectomy, PEG insertion, endoscopy)

WARNING

Last updated by [user-role-label]

_____
(Last updated by)