Withdrawal notification

Participant ID

_____
(REDCap auto generated)

ISRCTN 40512746

Metoclopramide for Avoiding Pneumonia after Stroke Trial Withdrawal notification v1.0

Withdrawal

Participants are free to withdraw from the trial at any time without giving a reason. The participant will be asked if they wish to withdraw from any or all of: The trial treatment, follow-up with participant contact, or follow-up without participant contact.

Unless the participant withdraws from follow-up, this will be continued as per protocol.

If the participant declines continued personal participation, but allows data collection from other sources (such as the general practitioner and hospital databases), follow-up data will be collected via this route.

If the condition of the participant deteriorates and care changes to palliation, discontinuation of the trial medication will be at the discretion of the clinical care team. Withdrawal, and the reasons for withdrawal, if given, will be documented in the CRF.

Participant removal from the trial due to adverse events

In any participant who experiences an adverse event the trial medication may be withdrawn permanently or temporarily halted at the discretion of the Local Investigator. Should the participant not receive the complete intervention, they will remain in the trial and be followed up until the end of the trial, as completeness of follow-up is essential.

Section A: Participant details

A1. Centre name :

A2. Participant ID :

A3. Participant initials :

A4. Date of data collection

_____
(dd-mm-yyyy (day [day_calculated_pv]))

Section B: Withdrawal details

B1. Patient status

If deceased or withdrawn complete the "Vital status check/notification of death/withdrawal" CRF.

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

◯ Alive
◯ Discharged into the community
◯ Withdrawn & refused any follow-up
◯ Palliative care
◯ Died
◯ Unknown

B2. Date of Withdrawal	_____ (dd-mm-yyyy (day [day_calculated_withdraw_w]))
B3a. Withdrawal is requested by:	◯ Participant ◯ Legal representative ◯ Medical practitioner ◯ Family ◯ Principal investigator or delegated investigator ◯ Other (If other, please provide details)
B3b. If other, please specify withdrawn by	_____

B4. Participant wishes to withdraw from:

Unless the participant/ their representative expressly state they wish (b) and (c), withdrawal will only be from trial treatment (a).

B4a. Withdrawal from trial treatment	◯ Yes ◯ No
B4b. Withdrawal from in-person follow-up	◯ Yes ◯ No
B4c. Withdrawal from data collection not involving contact with the participant or named contact (e.g GP/ hospital data/ ONS)	◯ Yes ◯ No

Withdrawal reason

B5a. Participant provided withdrawal reason Participants are free to withdraw from the trial at any time without giving a reason.	◯ Participant does not wish to give a reason ◯ Adverse effect of the trial treatment (if this is ticked, please complete AE/SAE form) ◯ End of life/palliative care ◯ Other (please specify) (If other, please provide details)
B5b. If other withdrawal reason, please specify	_____

Section C: Signature

C1. Name of person completing the form	_____
C2. "I confirm that the contents of this form are accurate and complete"	_____

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

_____