

Withdrawal Notification

Participant ID

(REDCap auto generated)



Metoclopramide for Avoiding Pneumonia after Stroke Trial

CRF: Withdrawal notification v1.2

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In any participant who experiences an adverse event the trial medication may be withdrawn permanently or temporarily halted at the discretion of the Local Investigator.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_w]))

Section B: Withdrawal details

B1. If reporting a death, please complete the "Notification of death" CRF.

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 If other, please specify withdrawn by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 and follow-ups

- ☐ Withdraw from trial treatment only
☐ Withdraw from trial treatment and further follow-ups
☐ Continue treatment but withdraw from further follow-ups

B4b. Further follow-ups: in-person

- ☐ Withdrawn from in-person follow-up
☐ Not withdrawn from In-person follow-up

B4c. Further follow-ups: other contact

(e.g GP/ hospital data/ ONS)

- ☐ Withdrawn from data collection not involving contact with the participant or named contact
☐ Not withdrawn from data collection not involving contact with the participant or named contact
☐ Old value

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. Username of person completing the form

C2a. Full name of person completing the form

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
