Protocol Violation

Participant ID

_____
(REDCap auto generated)

ISRCTN 40512746

Metoclopramide for Avoiding Pneumonia after Stroke Trial

Protocol Violation v1.2

Section A: Participant details

A1. Centre name :

A2. Participant ID:

A3. Participant initials :

Section B: Event Information

B1. Date of event:

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

B2. Type of protocol violation

- ◯ Patient randomised under 18 years old
- ◯ Randomisation > 25 hours symptom onset
- ◯ Patient randomised with NIHSS < 6
- ◯ Patient randomised with NIHSS >6, but no dysphagia
- ◯ Patient randomised with probable/definite pneumonia at screening
- ◯ Patient randomised with contraindication for metoclopramide
- ◯ Patient randomised with clinical indication for regular anti-sickness medication
- ◯ Patient randomised with known renal failure
- ◯ Patient randomised with known liver cirrhosis
- ◯ Pregnant / lactating patient randomised
- ◯ Patient randomised with life expectancy of < 3 months
- ◯ Patient randomised whilst co-enrolled in CTIMP without sponsor agreement
- ◯ Patient randomised without consent obtained from themselves or legal representative
- ◯ Consent taken by investigator not on delegation log
- ◯ Missed more than 8 doses over 14 days or given less than 80% of required doses in the treatment period
- ◯ Incorrect treatment given (patient given metoclopramide when prescribed placebo, and vice versa)
- ◯ 10mg/2ml dose given to patient weighing < 60kg
- ◯ Failure to report SAE / SUSAR within 24hrs of knowledge of event
- ◯ Incorrect route of trial treatment administration
- ◯ Any other deviation/violation not mentioned above (please specify)

(Choose one answer)

B3. Full explanation / comments

_____

(Free text)

Section C: Signature

C1. Name of person completing the form

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(Free text)