

Form 1: Trial Entry

Use this form:

- When written informed parental consent has been obtained
- When infant is ready to be randomised

Complete Section A prior to randomisation

ELFIN

Infant's surname: _____

Infant's first name: *(enter unknown if applicable)* _____

Name of hospital: _____



Section A: Enrolment

- A.1 Is this infant's gestational age at birth less than 32 weeks? Yes No
- A.2 Is this infant less than 72 hours old? Yes No
- A.3 Infant's date and time of birth: (use 24hr clock) / / : 24hr
- A.4 Infant's expected date of delivery (EDD):
(by maternal scan if available, not LMP) / /
- A.5 Infant's birth weight: g
- A.6 Does this infant have a severe congenital anomaly? Yes No
- A.7 Is this infant expected to fast enterally for more than 14 days? Yes No
- A.8 Does this infant have a realistic prospect of survival? Yes No
- A.9 Has written informed parental consent been obtained? Yes No

If Yes, please PRINT name of person who obtained consent:

If Yes, please PRINT name of hospital where consent obtained:

- A.10 What is this infant's sex? Male Female Indeterminate
- A.11 Is this infant a singleton or multiple fetus? Singleton Multiple
- A.12 Infant's NHS number: (if available)

Section B: Randomisation

- B.1 ELFIN study number:
- B.2 Treatment Pack ID:

Section C: Neonatal details

- C.1 Was this infant delivered via caesarean section? Yes No
- C.2 Were the membranes ruptured before labour? Yes No
- C.3 Were the membranes ruptured >24 hours before delivery? Yes No
- C.4 Was this infant's heart rate >100 bpm at 5 minutes of age? Yes No
- C.5 What was this infant's temperature when first admitted to the first neonatal unit? . °C
- C.6 What was this infant's worst base excess measured within 24 hours of birth? (if positive change - to +) - .
- C.7 Was this infant ventilated via an endotracheal tube at the time of randomisation? Yes No
- C.8 Did this infant have absent or reversed end diastolic flow identified on any antenatal ultrasound scan? Yes No
- C.9 If this infant was one of a multiple pregnancy:
 - How many infants were born?
 - What was the birth order of this infant?

Section D: Maternal details

- D.1 Did the mother receive antenatal corticosteroids? Yes No
- D.2 Mother's surname: _____
- D.3 Mother's first name: _____
- D.4 Mother's NHS number:
- D.5 Mother's date of birth: / /
- D.6 Main language: _____
- D.7 Mother's email address: _____
- D.8 Mother's mobile number: _____

Section E: Form details

Details of person completing form

Name: _____

Role: _____

Date: / / Signature: _____

When this form has been completed

Please return within 7 days of randomisation to the ELFIN Coordinating Centre using the FREEPOST envelope provided



Contact Details

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For URGENT queries outside office hours telephone 0800 138 5451
and leave a message with the operator.

