# Randomisation - Eligibility

calories

## Admission to your critical care unit

Date: D D / M M / 2 0 Y Y  Time: H H : M M (24-hour clock)

## Original admission to critical care

Patient admitted direct from another critical care unit: Yes (Y) No (N)

**If yes**

Date of original admission: D D / M M / 2 0 Y Y  Time of original admission: H H : M M (24-hour clock)

## Inclusion

Age (18 years or over): ☐☐

Needs artificial nutrition for two or more days: (use clinical judgement) Yes (Y)

Unplanned admission (including planned now unplanned): Yes (Y)

No planned discharge within three days: (use clinical judgement) Yes (Y)

## Exclusion

Burns patient: No (N)

Received PN/EN in last seven days: No (N)

Admitted for palliative care: No (N)

Known pregnancy: No (N)

Percutaneous endoscopic gastrostomy/jejunostomy or needle/surgical jejunostomy in situ: No (N)

Expected stay in UK less than six months: No (N)

Pre-existing contraindication to PN/EN: No (N)

Previously randomised into CALORIES: No (N)

***N.B. If during screening, a patient is found to be participating in another interventional study/trial, then please contact the ICNARC CTU on [redacted] to discuss their participation in CALORIES***

## Surgical/Malnutrition status

Surgery within 24 hours prior to critical care: Yes (Y) No (N)

Malnourished: (use clinical judgement) Yes (Y) No (N)

## Consent/Agreement

Process used: Patient consent (1) Personal Consultee (2) Professional Consultee (3)

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## Randomisation

Treatment allocation:

Early nutritional support via **parenteral route** (PN)

Early nutritional support via **enteral route** (EN)

Trial number: ☐☐☐☐

### Date and time of randomisation:

Date: D D / M M / 2 0 Y Y  Time: H H : M M (24-hour clock)

### Please start nutritional support ASAP and no later than:

Date: D D / M M / 2 0 Y Y  Time: H H : M M (24-hour clock)

**Completed by:** (print name) _____ **Signature:** _____

# Randomisation – Eligibility

To be completed once consent/agreement is obtained and before calling the Randomisation Service

**Admission to your critical care unit**
Record the date and time of admission to your critical care unit.

**Original admission to critical care**
If the patient was admitted to your critical care unit from another critical care unit, record the date and time of the original admission.

**Inclusion** – all should be ticked 'Yes' to be eligible.

**Exclusion** – all should be ticked 'No' to be eligible.

**Surgical/Malnutrition status**
Surgery within 24 hours prior to critical care – i.e within 24 hours prior to original admission to critical care. Surgery is defined as undergoing all or part of a surgical procedure or anaesthesia for a surgical procedure in an operating theatre or an anaesthetic room.

Malnourished (use clinical judgement) – indicate whether you consider the patient to be malnourished.

**Consent/Agreement**
Process used
Patient consent – the patient provided informed consent.
Personal Consultee – a relative or friend provided agreement.
Professional Consultee – an Independent Mental Capacity Advocate provided agreement.

**Randomisation**
Treatment allocation – provided by the Randomisation Service.

Trial number – enter 4-digit number, provided by the Randomisation Service.

**Information needed by site to randomise a patient**
Randomisation Service – [redacted]
Study number – 6551
Investigator number – XXX

calories

icnarc intensive care national audit & research centre

# A phase III, open, multicentre randomised controlled trial comparing the clinical and cost-effectiveness of early nutritional support in critically ill patients via the parenteral versus the enteral route

# Case Report Form

**Investigator number**

| | | |
|---|---|---|
| | | |

**Trial number**

| | | | |
|---|---|---|---|
| | | | |

**Treatment allocation**

Early nutritional support via parenteral route — PN

Early nutritional support via enteral route — EN

**Date and time of randomisation**

Date: D D / M M / 2 0 Y Y  Time: H H : M M (24-hour clock)

**Please start nutritional support ASAP and no later than**

Date: D D / M M / 2 0 Y Y  Time: H H : M M (24-hour clock)

# Randomisation/Minimisation criteria

*(results confirming inclusion/minimisation criteria)*

calories

Trial number: | | | | |

## Inclusion criteria

Date of birth: D D / M M / 1 9 Y Y

### Surgery

Surgery within 24 hours prior to admission to critical care: Yes (Y) No (N)

**If yes**

Date: D D / M M / 2 0 Y Y  Time: H H : M M (24-hour clock)

### Malnutrition status

Weight: | | | kg  Estimated:

Height: | | | cm  Estimated: Yes (Y) No (N)

Ulna length: | | . | cm  Mid-upper arm circumference (MUAC): | | cm

Weight loss (past six months):

- 0 to 5% (L)
- 5 to 10% (T)
- Greater than 10% (G)

Extent of oedema:

- None (NO)
- Mild (MI)
- Moderate (MO)
- Severe (SE)

## Actual start of randomly allocated nutritional support

Date: D D / M M / 2 0 Y Y  Time: H H : M M (24-hour clock)

## Comments

**Completed by:** (print name)

**Signature:**

**Date completed:** D D / M M / 2 0 Y Y

# Baseline - Contact details

calories

Trial number:

## Patient details

Title:

First name:

Surname:

Gender: Male (M) Female (F)

NHS number:

Hospital number:

Case Mix Programme Admission number:

House name/number:

Postcode:

Address 1:

Address 2:

City:

County:

Country:

**If address not known**

Residence/status: Abroad (A) Military (M) Homeless (H) No fixed abode (N)

Telephone number:

Mobile number:

Other number:

## Primary care details

Initials:

Surname:

Practice name:

House name/number:

Postcode:

Address 1:

Address 2:

City:

County:

Country:

## Comments

**Completed by:** (print name)

**Signature:**

**Date completed:** D D / M M / 2 0 Y Y

# Baseline - Physiology/Interventions

*(within 24 hours prior to randomisation)*

calories

Trial number: ☐☐☐☐

## Physiology

**Lowest P/F ratio:**

$PaO_2$: ☐☐☐.☐ kPa (K) mmHg (M) (NR)

$FiO_2$: ☐.☐☐

P/F ratio on mechanical ventilation: Yes (Y) No (N)

Lowest MAP: ☐☐☐ mmHg **or**

Lowest SBP/DBP: ☐☐☐/☐☐☐ mmHg (NR)

Not recorded (NR)

Lowest platelets: ☐☐☐☐ $x10^9\ l^{-1}$ (NR)

Highest bilirubin: ☐☐☐.☐ $\mu mol\ l^{-1}$ (NR)

Highest creatinine: ☐☐☐☐ $\mu mol\ l^{-1}$ (NR)

Urine output: ☐☐☐☐ ml (NR)

Not recorded (NR)

## Glasgow Coma Score (GCS)

Lowest total GCS: ☐☐

| Eye opening response | | Motor response | | Verbal response | |
|---|---|---|---|---|---|
| Spontaneous | 4 | Obeys commands | 6 | Oriented | 5 |
| To speech | 3 | Localises to painful stimuli | 5 | Confused | 4 |
| To painful stimulation | 2 | Withdrawal to painful stimuli | 4 | Inappropriate words | 3 |
| No response | 1 | Abnormal flexion | 3 | Incomprehensible sounds | 2 |
| | | Extends to painful stimuli | 2 | No response | 1 |
| | | No response | 1 | | |

Pre-sedation value: Yes (Y) No (N)

Not recorded: (NR)

## Interventions

Vasoactives administered: Yes (Y) No (N)

**If yes**

Epinephrine: Yes (Y) → Max. rate: ≤0.1 µg $kg^{-1}$ $min^{-1}$ (L); >0.1 µg $kg^{-1}$ $min^{-1}$ (U)

Dopamine: Yes (Y) → Max. rate: ≤5 µg $kg^{-1}$ $min^{-1}$ (L); >5 µg $kg^{-1}$ $min^{-1}$ (M); >15 µg $kg^{-1}$ $min^{-1}$ (U)

Norepinephrine: Yes (Y) → Max. rate: ≤0.1 µg $kg^{-1}$ $min^{-1}$ (L); >0.1 µg $kg^{-1}$ $min^{-1}$ (U)

Dobutamine: Yes (Y)

## Comments

**Completed by:** (print name)

**Signature:**

**Date completed:** DD/MM/20YY

# Day 1 - Nutritional support *(from start to 23:59)*

calories

Trial number: ☐☐☐☐

D D / M M / 2 0 Y Y

## Nutritional support

Route:

Parenteral (PN) → Jugular (J) Subclavian (S) Femoral (F) PICC (P) Other (O) → Specify other: ☐

Product: ☐ Total volume: ☐☐☐☐ ml

Additives:

Glutamine: Yes (Y) No (N) Fish oils: Yes (Y) No (N)

Selenium: Yes (Y) No (N)

Enteral (EN) → Nose (N) Mouth (M) Percutaneous (P)

Stomach (S) Duodenum (D) Jejunum (J) Other (O) → Specify other: ☐

Product: ☐ Total volume: ☐☐☐☐ ml

Total volume of aspirates: ☐☐☐☐ ml Total volume 'put back': ☐☐☐☐ ml

Prokinetics: Yes (Y) No (N)

Exclusive oral feeding (O)

## Change to nutritional support

Change either to route/site/product or a change to exclusive oral feeding: Yes (Y) No (N)

**If yes, then please complete Change to nutritional support form and attach to CRF**

## Other energy sources

IV glucose: Yes (Y) No (N) **If yes** ☐☐% ☐☐☐☐ ml ☐☐% ☐☐☐☐ ml ☐☐% ☐☐☐☐ ml

Propofol: Yes (Y) No (N) **If yes** 1% ☐☐☐☐ ml 2% ☐☐☐☐ ml

Oral feed: Yes (Y) No (N) **If yes** Product: ☐ Total: ☐☐☐☐ ☐ ml ☐ calories

## Insulin

Insulin: Yes (Y) No (N) **If yes** Total units: ☐☐☐ IU

## Stools

Bowels open: Yes (Y) No (N) Unable to assess (U)

Hard and formed (1) Soft and formed (2) Loose and unformed (3) Liquid (4)

## Infectious episodes and Adverse events

New infectious episode: Yes (Y) No (N) **If yes, then please complete Infectious episodes form (page 34)**

Adverse event related to trial treatment: Yes (Y) No (N) **If yes, then please complete Safety monitoring form (page 38)**

**Completed by:** (print name) ☐

**Signature:** ☐ **Date completed:** D D / M M / 2 0 Y Y

# Day 1 – Physiology/Interventions

*(from start to 23:59)*

calories

Trial number: ☐☐☐☐

## Physiology

Not recorded (NR)

**Lowest P/F ratio:**

$PaO_2$: ☐☐☐.☐ kPa (K) mmHg (M) (NR)

$FiO_2$: ☐.☐☐

P/F ratio on mechanical ventilation: Yes (Y) No (N)

Lowest MAP: ☐☐☐ mmHg **or** (NR)

Lowest SBP/DBP: ☐☐☐/☐☐☐ mmHg

Lowest glucose: ☐☐☐.☐ $mmol^{-1}$ (NR)

Highest glucose: ☐☐☐.☐ $mmol^{-1}$ (NR)

Not recorded (NR)

Lowest Albumin: ☐☐.☐ $g\ l^{-1}$ (NR)

Highest AST: ☐☐☐☐☐ $units\ l^{-1}$ (NR)

Highest ALP: ☐☐☐☐ $units\ l^{-1}$ (NR)

Highest ALT: ☐☐☐☐☐ $units\ l^{-1}$ (NR)

Lowest platelets: ☐☐☐☐ $x10^9\ l^{-1}$ (NR)

Highest bilirubin: ☐☐☐.☐ $\mu mol^{-1}$ (NR)

Highest creatinine: ☐☐☐☐ $\mu mol^{-1}$ (NR)

Urine output: ☐☐☐☐ ml (NR)

## Glasgow Coma Score (GCS)

Lowest total GCS: ☐☐

| Eye opening response | | Motor response | | Verbal response | |
|---|---|---|---|---|---|
| Spontaneous | 4 | Obeys commands | 6 | Oriented | 5 |
| To speech | 3 | Localises to painful stimuli | 5 | Confused | 4 |
| To painful stimulation | 2 | Withdrawal to painful stimuli | 4 | Inappropriate words | 3 |
| No response | 1 | Abnormal flexion | 3 | Incomprehensible sounds | 2 |
| | | Extends to painful stimuli | 2 | No response | 1 |
| | | No response | 1 | | |

Pre-sedation value: Yes (Y) No (N)

Not recorded: (NR)

## Interventions

Vasoactives administered: Yes (Y) No (N)

**If yes**

Epinephrine: Yes (Y) → Max. rate: ≤0.1 µg $kg^{-1}$ $min^{-1}$ (L); >0.1 µg $kg^{-1}$ $min^{-1}$ (U)

Dopamine: Yes (Y) → Max. rate: ≤5 µg $kg^{-1}$ $min^{-1}$ (L); >5 µg $kg^{-1}$ $min^{-1}$ (M); >15 µg $kg^{-1}$ $min^{-1}$ (U)

Norepinephrine: Yes (Y) → Max. rate: ≤0.1 µg $kg^{-1}$ $min^{-1}$ (L); >0.1 µg $kg^{-1}$ $min^{-1}$ (U)

Dobutamine: Yes (Y)

Systemic antibacterials: Yes (Y) No (N)

**If yes** Prophylactic (P) Therapeutic (T)

Systemic antifungals: Yes (Y) No (N)

**If yes** Prophylactic (P) Therapeutic (T)

**Completed by:** (print name) ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

**Signature:** ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

**Date completed:** D D / M M / 2 0 Y Y

# Day 2 - Nutritional support *(from 00:00 to 23:59)*

calories

Trial number: [ ][ ][ ][ ]

D D / M M / 2 0 Y Y

## Nutritional support

Route:

Parenteral (PN) → Jugular (J) Subclavian (S) Femoral (F) PICC (P) Other (O) → Specify other:

Product: Total volume: ml

Additives:

Glutamine: Yes (Y) No (N) Fish oils: Yes (Y) No (N)

Selenium: Yes (Y) No (N)

Enteral (EN) → Nose (N) Mouth (M) Percutaneous (P)

Stomach (S) Duodenum (D) Jejunum (J) Other (O) → Specify other:

Product: Total volume: ml

Total volume of aspirates: ml Total volume 'put back': ml

Prokinetics: Yes (Y) No (N)

Exclusive oral feeding (O)

## Change to nutritional support

Change either to route/site/product or a change to exclusive oral feeding: Yes (Y) No (N)

**If yes, then please complete Change to nutritional support form and attach to CRF**

## Other energy sources

IV glucose: Yes (Y) No (N) **If yes** [ ][ ]% [ ][ ][ ][ ] ml [ ][ ]% [ ][ ][ ][ ] ml [ ][ ]% [ ][ ][ ][ ] ml

Propofol: Yes (Y) No (N) **If yes** 1% [ ][ ][ ][ ] ml 2% [ ][ ][ ][ ] ml

Oral feed: Yes (Y) No (N) **If yes** Product: Total: [ ][ ][ ][ ] ml calories

## Insulin

Insulin: Yes (Y) No (N) **If yes** Total units: [ ][ ][ ] IU

## Stools

Bowels open: Yes (Y) No (N) Unable to assess (U)

Hard and formed (1) Soft and formed (2) Loose and unformed (3) Liquid (4)

## Infectious episodes and Adverse events

New infectious episode: Yes (Y) No (N) **If yes, then please complete Infectious episodes form (page 34)**

Adverse event related to trial treatment: Yes (Y) No (N) **If yes, then please complete Safety monitoring form (page 38)**

**Completed by:** (print name)

**Signature:**

**Date completed:** D D / M M / 2 0 Y Y

# Day 2 – Physiology/Interventions

*(from 00:00 to 23:59)*

calories

Trial number: ☐☐☐☐

## Physiology

**Lowest P/F ratio:**

$PaO_2$: ☐☐☐ · ☐ kPa (K) mmHg (M) (NR)

$FiO_2$: ☐ · ☐☐

P/F ratio on mechanical ventilation: Yes (Y) No (N)

Lowest MAP: ☐☐☐ mmHg **or** (NR)

Lowest SBP/DBP: ☐☐☐/☐☐☐ mmHg

Lowest glucose: ☐☐☐ · ☐ $mmol^{-1}$ (NR)

Highest glucose: ☐☐☐ · ☐ $mmol^{-1}$ (NR)

Not recorded (NR)

Lowest Albumin: ☐☐ · ☐ $g\ l^{-1}$ (NR)

Highest AST: ☐☐☐☐☐ $units\ l^{-1}$ (NR)

Highest ALP: ☐☐☐☐ $units\ l^{-1}$ (NR)

Highest ALT: ☐☐☐☐☐ $units\ l^{-1}$ (NR)

Lowest platelets: ☐☐☐☐ $x10^9\ l^{-1}$ (NR)

Highest bilirubin: ☐☐☐ · ☐ $\mu mol^{-1}$ (NR)

Highest creatinine: ☐☐☐☐ $\mu mol^{-1}$ (NR)

Urine output: ☐☐☐☐ ml (NR)

## Glasgow Coma Score (GCS)

Lowest total GCS: ☐☐

| Eye opening response | | Motor response | | Verbal response | |
|---|---|---|---|---|---|
| Spontaneous | 4 | Obeys commands | 6 | Oriented | 5 |
| To speech | 3 | Localises to painful stimuli | 5 | Confused | 4 |
| To painful stimulation | 2 | Withdrawal to painful stimuli | 4 | Inappropriate words | 3 |
| No response | 1 | Abnormal flexion | 3 | Incomprehensible sounds | 2 |
| | | Extends to painful stimuli | 2 | No response | 1 |
| | | No response | 1 | | |

Pre-sedation value: Yes (Y) No (N)

Not recorded: (NR)

## Interventions

Vasoactives administered: Yes (Y) No (N)

**If yes**

Epinephrine: Yes (Y) → Max. rate → ≤0.1 µg $kg^{-1}$ $min^{-1}$ (L); >0.1 µg $kg^{-1}$ $min^{-1}$ (U)

Dopamine: Yes (Y) → Max. rate → ≤5 µg $kg^{-1}$ $min^{-1}$ (L); >5 µg $kg^{-1}$ $min^{-1}$ (M); >15 µg $kg^{-1}$ $min^{-1}$ (U)

Norepinephrine: Yes (Y) → Max. rate → ≤0.1 µg $kg^{-1}$ $min^{-1}$ (L); >0.1 µg $kg^{-1}$ $min^{-1}$ (U)

Dobutamine: Yes (Y)

Systemic antibacterials: Yes (Y) No (N)

**If yes**

Prophylactic (P) Therapeutic (T)

Systemic antifungals: Yes (Y) No (N)

**If yes**

Prophylactic (P) Therapeutic (T)

**Completed by:** (print name) ☐

**Signature:** ☐

**Date completed:** D D / M M / 2 0 Y Y

# Day 3 - Nutritional support *(from 00:00 to 23:59)*

calories

Trial number: [ ][ ][ ][ ]

D D / M M / 2 0 Y Y

## Nutritional support

Route:

Parenteral (PN) → Jugular (J) Subclavian (S) Femoral (F) PICC (P) Other (O) → Specify other:

Product: Total volume: ml

Additives:

Glutamine: Yes (Y) No (N) Fish oils: Yes (Y) No (N)

Selenium: Yes (Y) No (N)

Enteral (EN) → Nose (N) Mouth (M) Percutaneous (P)

Stomach (S) Duodenum (D) Jejunum (J) Other (O) → Specify other:

Product: Total volume: ml

Total volume of aspirates: ml Total volume 'put back': ml

Prokinetics: Yes (Y) No (N)

Exclusive oral feeding (O)

## Change to nutritional support

Change either to route/site/product or a change to exclusive oral feeding: Yes (Y) No (N)

**If yes, then please complete Change to nutritional support form and attach to CRF**

## Other energy sources

IV glucose: Yes (Y) No (N) **If yes** [ ]% [ ]ml [ ]% [ ]ml [ ]% [ ]ml

Propofol: Yes (Y) No (N) **If yes** 1% [ ]ml 2% [ ]ml

Oral feed: Yes (Y) No (N) **If yes** Product: Total: [ ]ml [ ]calories

## Insulin

Insulin: Yes (Y) No (N) **If yes** Total units: IU

## Stools

Bowels open: Yes (Y) No (N) Unable to assess (U)

Hard and formed (1) Soft and formed (2) Loose and unformed (3) Liquid (4)

## Infectious episodes and Adverse events

New infectious episode: Yes (Y) No (N) **If yes, then please complete Infectious episodes form (page 34)**

Adverse event related to trial treatment: Yes (Y) No (N) **If yes, then please complete Safety monitoring form (page 38)**

**Completed by:** (print name)

**Signature:**

**Date completed:** D D / M M / 2 0 Y Y

# Day 3 – Physiology/Interventions

*(from 00:00 to 23:59)*

calories

Trial number: ☐☐☐☐

## Physiology

**Lowest P/F ratio:**

$PaO_2$: ☐☐☐.☐ kPa (K) mmHg (M) (NR)

$FiO_2$: ☐.☐☐

P/F ratio on mechanical ventilation: Yes (Y) No (N)

Lowest MAP: ☐☐☐ mmHg **or** (NR)

Lowest SBP/DBP: ☐☐☐/☐☐☐ mmHg

Lowest glucose: ☐☐☐.☐ $mmol^{-1}$ (NR)

Highest glucose: ☐☐☐.☐ $mmol^{-1}$ (NR)

Not recorded (NR)

Lowest Albumin: ☐☐.☐ $g\ l^{-1}$ (NR)

Highest AST: ☐☐☐☐☐ $units\ l^{-1}$ (NR)

Highest ALP: ☐☐☐☐ $units\ l^{-1}$ (NR)

Highest ALT: ☐☐☐☐☐ $units\ l^{-1}$ (NR)

Lowest platelets: ☐☐☐☐ $x10^9\ l^{-1}$ (NR)

Highest bilirubin: ☐☐☐.☐ $\mu mol^{-1}$ (NR)

Highest creatinine: ☐☐☐☐ $\mu mol^{-1}$ (NR)

Urine output: ☐☐☐☐ ml (NR)

Not recorded (NR)

## Glasgow Coma Score (GCS)

Lowest total GCS: ☐☐

| Eye opening response | | Motor response | | Verbal response | |
|---|---|---|---|---|---|
| Spontaneous | 4 | Obeys commands | 6 | Oriented | 5 |
| To speech | 3 | Localises to painful stimuli | 5 | Confused | 4 |
| To painful stimulation | 2 | Withdrawal to painful stimuli | 4 | Inappropriate words | 3 |
| No response | 1 | Abnormal flexion | 3 | Incomprehensible sounds | 2 |
| | | Extends to painful stimuli | 2 | No response | 1 |
| | | No response | 1 | | |

Pre-sedation value: Yes (Y) No (N)

Not recorded: (NR)

## Interventions

Vasoactives administered: Yes (Y) No (N)

**If yes**

Epinephrine: Yes (Y) → Max. rate: ≤0.1 µg $kg^{-1}$ $min^{-1}$ (L); >0.1 µg $kg^{-1}$ $min^{-1}$ (U)

Dopamine: Yes (Y) → Max. rate: ≤5 µg $kg^{-1}$ $min^{-1}$ (L); >5 µg $kg^{-1}$ $min^{-1}$ (M); >15 µg $kg^{-1}$ $min^{-1}$ (U)

Norepinephrine: Yes (Y) → Max. rate: ≤0.1 µg $kg^{-1}$ $min^{-1}$ (L); >0.1 µg $kg^{-1}$ $min^{-1}$ (U)

Dobutamine: Yes (Y)

Systemic antibacterials: Yes (Y) No (N)

**If yes** Prophylactic (P) Therapeutic (T)

Systemic antifungals: Yes (Y) No (N)

**If yes** Prophylactic (P) Therapeutic (T)

**Completed by:** (print name)

**Signature:**

**Date completed:** D D / M M / 2 0 Y Y

# Day 4 - Nutritional support *(from 00:00 to 23:59)*

calories

Trial number: ☐☐☐☐

D D / M M / 2 0 Y Y

## Nutritional support

Route:

Parenteral (PN) → Jugular (J) Subclavian (S) Femoral (F) PICC (P) Other (O) → Specify other: ☐

Product: ☐ Total volume: ☐☐☐☐ ml

Additives:

Glutamine: Yes (Y) No (N) Fish oils: Yes (Y) No (N)

Selenium: Yes (Y) No (N)

Enteral (EN) → Nose (N) Mouth (M) Percutaneous (P)

Stomach (S) Duodenum (D) Jejunum (J) Other (O) → Specify other: ☐

Product: ☐ Total volume: ☐☐☐☐ ml

Total volume of aspirates: ☐☐☐☐ ml Total volume 'put back': ☐☐☐☐ ml

Prokinetics: Yes (Y) No (N)

Exclusive oral feeding (O)

## Change to nutritional support

Change either to route/site/product or a change to exclusive oral feeding: Yes (Y) No (N)

**If yes, then please complete Change to nutritional support form and attach to CRF**

## Other energy sources

IV glucose: Yes (Y) No (N) **If yes** ☐☐% ☐☐☐☐ ml ☐☐% ☐☐☐☐ ml ☐☐% ☐☐☐☐ ml

Propofol: Yes (Y) No (N) **If yes** 1% ☐☐☐☐ ml 2% ☐☐☐☐ ml

Oral feed: Yes (Y) No (N) **If yes** Product: ☐ Total: ☐☐☐☐ ☐ ml ☐ calories

## Insulin

Insulin: Yes (Y) No (N) **If yes** Total units: ☐☐☐ IU

## Stools

Bowels open: Yes (Y) No (N) Unable to assess (U)

Hard and formed (1) Soft and formed (2) Loose and unformed (3) Liquid (4)

## Infectious episodes and Adverse events

New infectious episode: Yes (Y) No (N) **If yes, then please complete Infectious episodes form (page 34)**

Adverse event related to trial treatment: Yes (Y) No (N) **If yes, then please complete Safety monitoring form (page 38)**

**Completed by:** (print name) ☐

**Signature:** ☐ **Date completed:** D D / M M / 2 0 Y Y

# Day 4 – Physiology/Interventions

*(from 00:00 to 23:59)*

calories

Trial number: ☐☐☐☐

## Physiology

Not recorded (NR)

**Lowest P/F ratio:**

$PaO_2$: ☐☐☐.☐ kPa (K) mmHg (M) (NR)

$FiO_2$: ☐.☐☐

P/F ratio on mechanical ventilation: Yes (Y) No (N)

Lowest MAP: ☐☐☐ mmHg **or**

Lowest SBP/DBP: ☐☐☐/☐☐☐ mmHg (NR)

Lowest glucose: ☐☐☐.☐ $mmol^{-1}$ (NR)

Highest glucose: ☐☐☐.☐ $mmol^{-1}$ (NR)

Not recorded (NR)

Lowest Albumin: ☐☐.☐ $g\ l^{-1}$ (NR)

Highest AST: ☐☐☐☐☐ $units\ l^{-1}$ (NR)

Highest ALP: ☐☐☐☐ $units\ l^{-1}$ (NR)

Highest ALT: ☐☐☐☐☐ $units\ l^{-1}$ (NR)

Lowest platelets: ☐☐☐☐ $x10^9\ l^{-1}$ (NR)

Highest bilirubin: ☐☐☐.☐ $\mu mol^{-1}$ (NR)

Highest creatinine: ☐☐☐☐ $\mu mol^{-1}$ (NR)

Urine output: ☐☐☐☐ ml (NR)

## Glasgow Coma Score (GCS)

Lowest total GCS: ☐☐

| Eye opening response | | Motor response | | Verbal response | |
|---|---|---|---|---|---|
| Spontaneous | 4 | Obeys commands | 6 | Oriented | 5 |
| To speech | 3 | Localises to painful stimuli | 5 | Confused | 4 |
| To painful stimulation | 2 | Withdrawal to painful stimuli | 4 | Inappropriate words | 3 |
| No response | 1 | Abnormal flexion | 3 | Incomprehensible sounds | 2 |
| | | Extends to painful stimuli | 2 | No response | 1 |
| | | No response | 1 | | |

Pre-sedation value: Yes (Y) No (N)

Not recorded: (NR)

## Interventions

Vasoactives administered: Yes (Y) No (N)

**If yes**

Epinephrine: Yes (Y) → Max. rate: ≤0.1 µg $kg^{-1}$ $min^{-1}$ (L); >0.1 µg $kg^{-1}$ $min^{-1}$ (U)

Dopamine: Yes (Y) → Max. rate: ≤5 µg $kg^{-1}$ $min^{-1}$ (L); >5 µg $kg^{-1}$ $min^{-1}$ (M); >15 µg $kg^{-1}$ $min^{-1}$ (U)

Norepinephrine: Yes (Y) → Max. rate: ≤0.1 µg $kg^{-1}$ $min^{-1}$ (L); >0.1 µg $kg^{-1}$ $min^{-1}$ (U)

Dobutamine: Yes (Y)

Systemic antibacterials: Yes (Y) No (N)

**If yes** Prophylactic (P) Therapeutic (T)

Systemic antifungals: Yes (Y) No (N)

**If yes** Prophylactic (P) Therapeutic (T)

**Completed by:** (print name) ☐

**Signature:** ☐

**Date completed:** D D / M M / 2 0 Y Y

# Day 5 - Nutritional support *(from 00:00 to 23:59)*

calories

Trial number:

D D / M M / 2 0 Y Y

## Nutritional support

Route:

Parenteral (PN) → Jugular (J) Subclavian (S) Femoral (F) PICC (P) Other (O) → Specify other:

Product: Total volume: ml

Additives:

Glutamine: Yes (Y) No (N) Fish oils: Yes (Y) No (N)

Selenium: Yes (Y) No (N)

Enteral (EN) → Nose (N) Mouth (M) Percutaneous (P)

Stomach (S) Duodenum (D) Jejunum (J) Other (O) → Specify other:

Product: Total volume: ml

Total volume of aspirates: ml Total volume 'put back': ml

Prokinetics: Yes (Y) No (N)

Exclusive oral feeding (O)

## Change to nutritional support

Change either to route/site/product or a change to exclusive oral feeding: Yes (Y) No (N)

**If yes, then please complete Change to nutritional support form and attach to CRF**

## Other energy sources

IV glucose: Yes (Y) No (N) **If yes** □□% ml □□% ml □□% ml

Propofol: Yes (Y) No (N) **If yes** 1% ml 2% ml

Oral feed: Yes (Y) No (N) **If yes** Product: Total: ml calories

## Insulin

Insulin: Yes (Y) No (N) **If yes** Total units: IU

## Stools

Bowels open: Yes (Y) No (N) Unable to assess (U)

Hard and formed (1) Soft and formed (2) Loose and unformed (3) Liquid (4)

## Infectious episodes and Adverse events

New infectious episode: Yes (Y) No (N) **If yes, then please complete Infectious episodes form (page 34)**

Adverse event related to trial treatment: Yes (Y) No (N) **If yes, then please complete Safety monitoring form (page 38)**

**Completed by:** (print name)

**Signature:**

**Date completed:** D D / M M / 2 0 Y Y

# Day 5 – Physiology/Interventions

*(from 00:00 to 23:59)*

calories

Trial number: ☐☐☐☐

## Physiology

**Lowest P/F ratio:**

$PaO_2$: ☐☐☐.☐ kPa (K) mmHg (M) (NR)

$FiO_2$: ☐.☐☐

P/F ratio on mechanical ventilation: Yes (Y) No (N)

Lowest MAP: ☐☐☐ mmHg **or** (NR)

Lowest SBP/DBP: ☐☐☐/☐☐☐ mmHg

Lowest glucose: ☐☐☐.☐ $mmol^{-1}$ (NR)

Highest glucose: ☐☐☐.☐ $mmol^{-1}$ (NR)

Not recorded (NR)

Lowest Albumin: ☐☐.☐ $g\ l^{-1}$ (NR)

Highest AST: ☐☐☐☐☐ $units\ l^{-1}$ (NR)

Highest ALP: ☐☐☐☐ $units\ l^{-1}$ (NR)

Highest ALT: ☐☐☐☐☐ $units\ l^{-1}$ (NR)

Lowest platelets: ☐☐☐☐ $x10^9\ l^{-1}$ (NR)

Highest bilirubin: ☐☐☐.☐ $\mu mol^{-1}$ (NR)

Highest creatinine: ☐☐☐☐ $\mu mol^{-1}$ (NR)

Urine output: ☐☐☐☐ ml (NR)

Not recorded (NR)

## Glasgow Coma Score (GCS)

Lowest total GCS: ☐☐

| Eye opening response | | Motor response | | Verbal response | |
|---|---|---|---|---|---|
| Spontaneous | 4 | Obeys commands | 6 | Oriented | 5 |
| To speech | 3 | Localises to painful stimuli | 5 | Confused | 4 |
| To painful stimulation | 2 | Withdrawal to painful stimuli | 4 | Inappropriate words | 3 |
| No response | 1 | Abnormal flexion | 3 | Incomprehensible sounds | 2 |
| | | Extends to painful stimuli | 2 | No response | 1 |
| | | No response | 1 | | |

Pre-sedation value: Yes (Y) No (N)

Not recorded: (NR)

## Interventions

Vasoactives administered: Yes (Y) No (N)

**If yes**

Epinephrine: Yes (Y) → Max. rate: ≤0.1 µg $kg^{-1}$ $min^{-1}$ (L); >0.1 µg $kg^{-1}$ $min^{-1}$ (U)

Dopamine: Yes (Y) → Max. rate: ≤5 µg $kg^{-1}$ $min^{-1}$ (L); >5 µg $kg^{-1}$ $min^{-1}$ (M); >15 µg $kg^{-1}$ $min^{-1}$ (U)

Norepinephrine: Yes (Y) → Max. rate: ≤0.1 µg $kg^{-1}$ $min^{-1}$ (L); >0.1 µg $kg^{-1}$ $min^{-1}$ (U)

Dobutamine: Yes (Y)

Systemic antibacterials: Yes (Y) No (N)

**If yes** Prophylactic (P) Therapeutic (T)

Systemic antifungals: Yes (Y) No (N)

**If yes** Prophylactic (P) Therapeutic (T)

**Completed by:** (print name)

**Signature:**

**Date completed:** D D / M M / 2 0 Y Y

# Day 6 - Nutritional support *(from 00:00 to 23:59)*

calories

Trial number: [ ][ ][ ][ ]

D D / M M / 2 0 Y Y

## Nutritional support

Route:

Parenteral (PN) → Jugular (J) Subclavian (S) Femoral (F) PICC (P) Other (O) → Specify other:

Product: Total volume: ml

Additives:

Glutamine: Yes (Y) No (N) Fish oils: Yes (Y) No (N)

Selenium: Yes (Y) No (N)

Enteral (EN) → Nose (N) Mouth (M) Percutaneous (P)

Stomach (S) Duodenum (D) Jejunum (J) Other (O) → Specify other:

Product: Total volume: ml

Total volume of aspirates: ml Total volume 'put back': ml

Prokinetics: Yes (Y) No (N)

Exclusive oral feeding (O)

## Change to nutritional support

Change either to route/site/product or a change to exclusive oral feeding: Yes (Y) No (N)

**If yes, then please complete Change to nutritional support form and attach to CRF**

## Other energy sources

IV glucose: Yes (Y) No (N) **If yes** [ ][ ]% [ ][ ][ ][ ] ml [ ][ ]% [ ][ ][ ][ ] ml [ ][ ]% [ ][ ][ ][ ] ml

Propofol: Yes (Y) No (N) **If yes** 1% [ ][ ][ ][ ] ml 2% [ ][ ][ ][ ] ml

Oral feed: Yes (Y) No (N) **If yes** Product: Total: [ ][ ][ ][ ] ml calories

## Insulin

Insulin: Yes (Y) No (N) **If yes** Total units: [ ][ ][ ] IU

## Stools

Bowels open: Yes (Y) No (N) Unable to assess (U)

Hard and formed (1) Soft and formed (2) Loose and unformed (3) Liquid (4)

## Infectious episodes and Adverse events

New infectious episode: Yes (Y) No (N) **If yes, then please complete Infectious episodes form (page 34)**

Adverse event related to trial treatment: Yes (Y) No (N) **If yes, then please complete Safety monitoring form (page 38)**

**Completed by:** (print name)

**Signature:**

**Date completed:** D D / M M / 2 0 Y Y

# Day 6 – Physiology/Interventions

*(from 00:00 to 23:59)*

calories

Trial number: ☐☐☐☐

## Physiology

**Lowest P/F ratio:**

$PaO_2$: ☐☐☐ . ☐ kPa (K) mmHg (M) (NR)

$FiO_2$: ☐ . ☐☐

P/F ratio on mechanical ventilation: Yes (Y) No (N)

Lowest MAP: ☐☐☐ mmHg **or**

Lowest SBP/DBP: ☐☐☐/☐☐☐ mmHg (NR)

Lowest glucose: ☐☐☐ . ☐ $mmol^{-1}$ (NR)

Highest glucose: ☐☐☐ . ☐ $mmol^{-1}$ (NR)

Not recorded (NR)

Lowest Albumin: ☐☐ . ☐ $g\ l^{-1}$ (NR)

Highest AST: ☐☐☐☐☐ $units\ l^{-1}$ (NR)

Highest ALP: ☐☐☐☐ $units\ l^{-1}$ (NR)

Highest ALT: ☐☐☐☐☐ $units\ l^{-1}$ (NR)

Lowest platelets: ☐☐☐☐ $x10^9\ l^{-1}$ (NR)

Highest bilirubin: ☐☐☐ . ☐ $\mu mol^{-1}$ (NR)

Highest creatinine: ☐☐☐☐ $\mu mol^{-1}$ (NR)

Urine output: ☐☐☐☐ ml (NR)

Not recorded (NR)

## Glasgow Coma Score (GCS)

Lowest total GCS: ☐☐

| Eye opening response | | Motor response | | Verbal response | |
|---|---|---|---|---|---|
| Spontaneous | 4 | Obeys commands | 6 | Oriented | 5 |
| To speech | 3 | Localises to painful stimuli | 5 | Confused | 4 |
| To painful stimulation | 2 | Withdrawal to painful stimuli | 4 | Inappropriate words | 3 |
| No response | 1 | Abnormal flexion | 3 | Incomprehensible sounds | 2 |
| | | Extends to painful stimuli | 2 | No response | 1 |
| | | No response | 1 | | |

Pre-sedation value: Yes (Y) No (N)

Not recorded: (NR)

## Interventions

Vasoactives administered: Yes (Y) No (N)

**If yes**

Epinephrine: Yes (Y) Max. rate → ≤0.1 μg $kg^{-1}$ $min^{-1}$ (L); >0.1 μg $kg^{-1}$ $min^{-1}$ (U)

Dopamine: Yes (Y) Max. rate → ≤5 μg $kg^{-1}$ $min^{-1}$ (L); >5 μg $kg^{-1}$ $min^{-1}$ (M); >15 μg $kg^{-1}$ $min^{-1}$ (U)

Norepinephrine: Yes (Y) Max. rate → ≤0.1 μg $kg^{-1}$ $min^{-1}$ (L); >0.1 μg $kg^{-1}$ $min^{-1}$ (U)

Dobutamine: Yes (Y)

Systemic antibacterials: Yes (Y) No (N)

**If yes** Prophylactic (P) Therapeutic (T)

Systemic antifungals: Yes (Y) No (N)

**If yes** Prophylactic (P) Therapeutic (T)

**Completed by:** (print name) ☐

**Signature:** ☐

**Date completed:** D D / M M / 2 0 Y Y

# Change of Nutritional Support (up to day 6)

calories

Trial number: | | | | |

## Date and estimated time of change of nutritional support

Date of change: D D / M M / 2 0 Y Y

Estimated time: H H : M M

## Nutritional support changed to

Route:

Parenteral (PN) → Jugular (J) Subclavian (S) Femoral (F) PICC (P) Other (O) → Specify other:

Product: Total volume: ml

Additives:

Glutamine: Yes (Y) No (N)

Fish oils: Yes (Y) No (N)

Selenium: Yes (Y) No (N)

Enteral (EN) → Nose (N) Mouth (M) Percutaneous (P)

Stomach (S) Duodenum (D) Jejunum (J) Other (O) → Specify other:

Product: Total volume: ml

Total volume of aspirates: ml

Total volume 'put back': ml

Prokinetics: Yes (Y) No (N)

Exclusive oral feeding (O)

## Comments

**Completed by:** (print name)

**Signature:**

**Date completed:** D D / M M / 2 0 Y Y

# At discharge from your critical care unit

calories
Trial number:

## Nutritional support in your critical care unit (from day 7 onwards)

| Route*: | Start date: |
|---|---|
| | D D / M M / 2 0 Y Y |
| | D D / M M / 2 0 Y Y |
| | D D / M M / 2 0 Y Y |
| | D D / M M / 2 0 Y Y |

*Route: *E=Enteral (exclusive), P=Parenteral (exclusive), O=Oral feeding (exclusive), EP=Enteral & Parenteral, EO=Enteral & Oral feeding, PO=Parenteral & Oral feeding, EPO=Enteral, Parenteral & Oral feeding*

## Interventions in your critical care unit (from day 7 onwards)

Systemic antibacterials: Yes (Y) No (N)

**If yes** Prophylactic (P) Therapeutic (T)

Systemic antifungals: Yes (Y) No (N)

**If yes** Prophylactic (P) Therapeutic (T)

## Organ support in your critical care unit (from randomisation onwards)

| | Total calendar days | | Total calendar days | | Total calendar days |
|---|---|---|---|---|---|
| Advanced respiratory: | | Renal: | | Dermatological: | |
| Basic respiratory: | | Neurological: | | Level 2: | |
| Advanced cardiovascular: | | Gastrointestinal: | | Level 3: | |
| Basic cardiovascular: | | Liver: | | | |

## Complications in your critical care unit (from randomisation onwards)

Pressure sores: Yes (Y) No (N)

**If yes** Staging: Stage I (I) Stage II (II) Stage III (III) Stage IV (IV)

Not recorded (NR) (NR)

## Infectious episodes in your critical care unit

**Please report ALL infectious episodes from day 7 to discharge from your critical care unit (page 34)**

## Status at discharge from your critical care unit

Alive: (A) → Date of discharge: D D / M M / 2 0 Y Y Time of discharge: H H : M M

Dead: (D) → Date of death: D D / M M / 2 0 Y Y Time of death: H H : M M

**Completed by:** (print name)

**Signature:**

**Date completed:** D D / M M / 2 0 Y Y

# Infectious episodes

*(from randomisation onwards to discharge from your critical care unit)*

calories

Trial number: | | | | |

## Strongly suspected or confirmed infections (specified)

| Clinical diagnosis[1]: | Confirmed[2]: | Start of treatment date: | Organism(s): |
|---|---|---|---|
| | Yes (Y) No (N) | D D / M M / 2 0 Y Y | |
| | | Treatment: | |
| | Yes (Y) No (N) | D D / M M / 2 0 Y Y | |
| | | | |
| | Yes (Y) No (N) | D D / M M / 2 0 Y Y | |
| | | | |
| | Yes (Y) No (N) | D D / M M / 2 0 Y Y | |
| | | | |
| | Yes (Y) No (N) | D D / M M / 2 0 Y Y | |
| | | | |
| | Yes (Y) No (N) | D D / M M / 2 0 Y Y | |
| | | | |

## Strongly suspected or confirmed infections (other)

| Clinical diagnosis: | Confirmed[2]: | Start of treatment date: | Organism(s): |
|---|---|---|---|
| | Yes (Y) No (N) | D D / M M / 2 0 Y Y | |
| | | Treatment: | |
| | Yes (Y) No (N) | D D / M M / 2 0 Y Y | |
| | | | |

[1]*Clinical diagnosis: B=Bloodstream infection, C=CVC infection, I=Infectious colitis, O=Other vascular catheter infection, P=Pneumonia, S=Surgical site infection, U=Urinary tract infection*

[2]*Confirmed = laboratory/microbiological confirmation*

**Completed by:** (print name)

**Signature:**

**Date completed:** D D / M M / 2 0 Y Y

# At discharge from your hospital

calories
Trial number:

## Change of location within your hospital (from discharge from your critical care unit)

From your critical care unit ®

| Location*: | Start date: | Start time: (24-hour clock) |
|---|---|---|
| | D D / M M / 2 0 Y Y | H H : M M |
| | D D / M M / 2 0 Y Y | H H : M M |
| | D D / M M / 2 0 Y Y | H H : M M |
| | D D / M M / 2 0 Y Y | H H : M M |
| | D D / M M / 2 0 Y Y | H H : M M |
| | D D / M M / 2 0 Y Y | H H : M M |

**Location:* *A=Acute Admissions Unit (or equivalent), W=Ward, I=ICU or ICU/HDU, H=HDU, E=Emergency Department, T=Theatre*

## Exclusive oral feeding

Exclusive oral feeding commenced since discharge from your critical care unit: Yes (Y) No (N)

**If yes**

Date exclusive oral feeding commenced: D D / M M / 2 0 Y Y

## Acute hospital discharge

Acute hospital discharge status (from your hospital): Alive (A) Dead (D)

**If alive**

Date of discharge: D D / M M / 2 0 Y Y

Discharge location:

- Home (H)
- Nursing Home (N)
- Transfer to other acute hospital (T)
- Other (O)

Specify

**If dead**

Date of death: D D / M M / 2 0 Y Y

Time of death: H H : M M

**Ultimate discharge from acute hospital:**

Status: Alive (A) Dead (D)

Date: D D / M M / 2 0 Y Y

**Note: Please obtain Retrospective consent prior to discharge**

## Comments

**Completed by:** (print name)

**Signature:**

**Date completed:** D D / M M / 2 0 Y Y

# Safety monitoring (SOP 013)

*(known adverse events from randomisation ® 30 days)*

calories

Trial number: | | | | |

## Adverse events (specified)

| | Severity[1]: | Start date: | Start time: (24-hour clock) | Related[2]: |
|---|---|---|---|---|
| Abdominal distension: | | D D / M M / 2 0 Y Y | H H : M M | |
| Abdominal pain: | | D D / M M / 2 0 Y Y | H H : M M | |
| Electrolyte disturbance: | | D D / M M / 2 0 Y Y | H H : M M | |
| Haemo-pneumothorax: | | D D / M M / 2 0 Y Y | H H : M M | |
| Hepatomegaly: | | D D / M M / 2 0 Y Y | H H : M M | |
| Hyperosmolar syndrome: | | D D / M M / 2 0 Y Y | H H : M M | |
| Hypersensitivity reaction (anaphylactic reaction): | | D D / M M / 2 0 Y Y | H H : M M | |
| Hypoglycaemia: | | D D / M M / 2 0 Y Y | H H : M M | |
| Ischaemic bowel: | | D D / M M / 2 0 Y Y | H H : M M | |
| Jaundice: | | D D / M M / 2 0 Y Y | H H : M M | |
| Nausea requiring treatment: | | D D / M M / 2 0 Y Y | H H : M M | |
| Pneumothorax: | | D D / M M / 2 0 Y Y | H H : M M | |
| Raised liver enzymes: | | D D / M M / 2 0 Y Y | H H : M M | |
| Regurgitation/aspiration: | | D D / M M / 2 0 Y Y | H H : M M | |
| Vascular catheter related infection: | | D D / M M / 2 0 Y Y | H H : M M | |
| Vomiting: | | D D / M M / 2 0 Y Y | H H : M M | |

## Adverse events (other)

| Adverse event: | Severity[1]: | Start date: | Start time: (24-hour clock) | Related[2]: |
|---|---|---|---|---|
| | | D D / M M / 2 0 Y Y | H H : M M | |
| | | D D / M M / 2 0 Y Y | H H : M M | |
| | | D D / M M / 2 0 Y Y | H H : M M | |
| | | D D / M M / 2 0 Y Y | H H : M M | |
| | | D D / M M / 2 0 Y Y | H H : M M | |
| | | D D / M M / 2 0 Y Y | H H : M M | |

*[1]Severity: 0=None, 1=Mild, 2=Moderate, 3=Severe, 4=Life-threatening, 5=Fatal*

*[2]Related (to trial treatment): 0=None, 1=Unlikely, 2=Possibly, 3=Probably, 4=Definitely*

**Note: If Severity 3 or more complete the Serious Adverse Event Reporting Form and fax to ICNARC CTU**

**Completed by:** (print name)

**Signature:**

**Date completed:** D D / M M / 2 0 Y Y

# Retrospective consent

calories
Trial number:

## Retrospective consent

Regained mental capacity: Yes (Y) No (N)

Retrospective consent:

- Obtained (O)
- Part-obtained (P)
- Refused (R)
- Not sought (N)

Date: D D / M M / 2 0 Y Y

**If part-obtained/not sought**

Details:

## Comments

**Completed by:** (print name)

**Signature:**

**Date completed:** D D / M M / 2 0 Y Y

# Death notification

calories

Trial number: | | | | |

Investigator number: | | | |

## Death

Date of death: D D / M M / 2 0 Y Y

If completed, return to ICNARC CTU

By fax: [redacted]
By email: [redacted]
By post: [redacted]

## Comments

**Completed by:** (print name)

**Signature:**

**Date completed:** D D / M M / 2 0 Y Y

# Withdrawal of consent/agreement

calories

Trial number: | | | | |

Investigator number: | | | |

## Withdrawal of consent/agreement

Date of withdrawal: D D / M M / 2 0 Y Y

Reason (if available):

Consent withdrawn by:

- Patient 1
- Personal Consultee 2
- Professional Consultee 3

If completed, return to ICNARC CTU

By fax: [redacted]
By email: [redacted]
By post: [redacted]

## Comments

**Completed by:** (print name)

**Signature:**

**Date completed:** D D / M M / 2 0 Y Y