Randomisation - Eligibility



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					
Date of original admission:	Time of original admission:				
Inclusion —					
Age (18 years or over):	Needs artificial nutrition for two or more days: (use clinical judgement)				
Unplanned admission (including planned now unplanned):	No planned discharge within three days: (use clinical judgement)				
Exclusion —					
Burns patient:	Received PN/EN in last seven days:				
Admitted for palliative care:	Known pregnancy:				
Percutaneous endoscopic gastrostomy/jejunostomy or needle/surgical jejunostomy in situ:	Expected stay in UK less than six months:				
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 a the ICNARC CTU on to discuss their participation in					
Surgical/Malnutrition status					
Surgery within 24 hours prior Yes Y No N					
Consent/Agreement —					
Process used: Patient consent 1 Personal Consultee 2 Professional Consultee 3					
Randomisation					
Treatment allocation: Early nutritional support via parenteral route Early nutritional support via enteral route Early nutritional support via enteral route					
☐ Date and time of randomisation:					
Date: D D M M Z 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

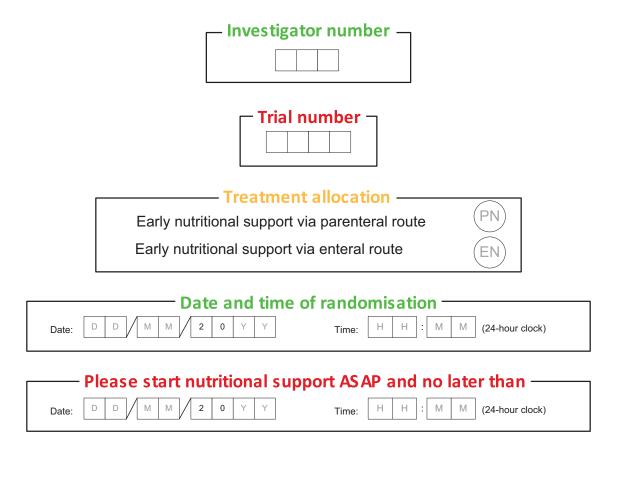
Randomisation Service – Study number – 6551 Investigator number – XXX





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



Randomisation/Minimisation criteria (results confirming inclusion/minimisation criteria)



Inclusion criteria ————————————————————————————————————					
Date of birth: DDMMM 1 9 YY					
_ 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% Extent of oedema: None					
5 to 10% T					
Greater than 10% G Moderate					
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					





Patient details ————————————————————————————————————	Primary care details —————
Title:	Initials:
First name:	Surname:
Surname:	Practice name:
Gender: Male M Female F	House name/number: Postcode:
NHS number:	Address 1:
Hospital number:	Address 2:
Case Mix Programme Admission number:	City:
House name/number:	County:
Postcode:	Country:
Address 1:	Comments
Address 2:	
City:	
County:	
Country:	
If address not known	
Residence/status: Abroad A Military	
Homeless H No fixed abode N	
Telephone number:	
Mobile number:	
Other number:	
Completed by:	
Completed by: (print name)	
Signature: Da	te completed: DDMMM200YY

Baseline - Physiology/Interventions (within 24 hours prior to randomisation)

calories

Not recorded (NR) Not recorded (I PaO ₂ :				
FiO ₂ :				
P/F ratio on mechanical ventilation: Yes Y No N Highest bilirubin: Liketest exactising: Highest practicing: Which are a statistical with the state of the st				
Lowest MAP: mmHg or Highest creatinine: µmol I ⁻¹ (N				
Lowest SBP/DBP: MmHg Urine output: M				
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				
No response 1 Abnormal flexion 3 Incomprehensible sounds 2				
Extends to painful stimuli 2 No response				
No response				
No response				
Pre-sedation value: Yes Y No N Not recorded: NR				
Interventions —				
Vasoactives administered: Yes (Y) No (N)				
If yes				
If yes ≤5 μg kg ⁻¹ min ⁻¹ (L				
If yes Epinephrine: Yes Max. rate Solve μg kg ⁻¹ min ⁻¹ Dopamine: Yes Max. rate Solve μg kg ⁻¹ min ⁻¹ Dopamine: Yes Max. rate Solve μg kg ⁻¹ min ⁻¹ Dopamine: Yes Max. rate				
If yes Epinephrine: Yes Max. rate So.1 μg kg ⁻¹ min ⁻¹ Dopamine: Yes Max. rate >5 μg kg ⁻¹ min ⁻¹ >5 μg kg ⁻¹ min ⁻¹ Σομφ kg ⁻¹ min ⁻¹ Σ				
If yes Epinephrine: Yes Max. rate So.1 μg kg ⁻¹ min ⁻¹ >0.1 μg kg ⁻¹ min ⁻¹ Dopamine: Yes Max. rate >5 μg kg ⁻¹ min ⁻¹ >5 μg kg ⁻¹ min ⁻¹				
If yes Epinephrine: Yes Max. rate So.1 μg kg ⁻¹ min ⁻¹ >0.1 μg kg ⁻¹ min ⁻¹ >1 Dopamine: Yes Max. rate So.1 μg kg ⁻¹ min ⁻¹ >5 μg kg ⁻¹ min ⁻¹ >1 μg kg ⁻¹ min ⁻¹ >1 μg kg ⁻¹ min ⁻¹ Nax. rate So.1 μg kg ⁻¹ min ⁻¹ Nax. rate				
If yes Epinephrine: Yes Max. rate So.1 μg kg ⁻¹ min ⁻¹ >0.1 μg kg ⁻¹ min ⁻¹ >1 Dopamine: Yes Max. rate Sing kg ⁻¹ min ⁻¹ >5 μg kg ⁻¹ min ⁻¹ >15 μg kg ⁻¹ min ⁻¹ >15 μg kg ⁻¹ min ⁻¹ >15 μg kg ⁻¹ min ⁻¹				
If yes Epinephrine: Yes Max. rate So.1 μg kg ⁻¹ min ⁻¹ >0.1 μg kg ⁻¹ min ⁻¹ >0.1 μg kg ⁻¹ min ⁻¹ Norepinephrine: Yes Max. rate So.1 μg kg ⁻¹ min ⁻¹ >10 Dopamine: Yes Max. rate So.1 μg kg ⁻¹ min ⁻¹ >10 Dobutamine: Yes Dobutamine: Yes Output Dobut				
If yes Epinephrine: Yes Max. rate So.1 μg kg ⁻¹ min ⁻¹ >0.1 μg kg ⁻¹ min ⁻¹ Dopamine: Yes Max. rate So.1 μg kg ⁻¹ min ⁻¹ Norepinephrine: Yes Dobutamine: Ye				
If yes Epinephrine: Yes Max. rate So.1 μg kg ⁻¹ min ⁻¹ >0.1 μg kg ⁻¹ min ⁻¹ >0.1 μg kg ⁻¹ min ⁻¹ Norepinephrine: Yes Max. rate So.1 μg kg ⁻¹ min ⁻¹ >10 Dopamine: Yes Max. rate So.1 μg kg ⁻¹ min ⁻¹ >10 Dobutamine: Yes Dobutamine: Yes Output Dobut				
If yes				
If yes Epinephrine: Yes Max. rate So.1 μg kg ⁻¹ min ⁻¹ >0.1 μg kg ⁻¹ min ⁻¹ >0.1 μg kg ⁻¹ min ⁻¹ Norepinephrine: Yes Max. rate So.1 μg kg ⁻¹ min ⁻¹ >10 Dopamine: Yes Max. rate So.1 μg kg ⁻¹ min ⁻¹ >10 Dobutamine: Yes Dobutamine: Yes Output Dobut				
If yes				
If yes Epinephrine: Yes Max. rate So.1 μg kg ⁻¹ min ⁻¹ >0.1 μg kg ⁻¹ min ⁻¹ >0.1 μg kg ⁻¹ min ⁻¹ Norepinephrine: Yes Max. rate So.1 μg kg ⁻¹ min ⁻¹ >10 Dopamine: Yes Max. rate So.1 μg kg ⁻¹ min ⁻¹ >10 Dobutamine: Yes Dobutamine: Yes Output Dobut				

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



Nutritional support			
Route: Parenteral PN Jugular J Subclavian S Femoral F PICC P Other O			
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			
Specify other:			
Stomach (S) Duodenum (D) Jejunum (J) Other (O)			
Product: Total volume: ml			
Total volume of aspirates: ml Total volume 'put back': ml			
Exclusive oral feeding Prokinetics: Yes Y No No N			
— Change to nutritional support			
Change either to route/site/product or a change to exclusive oral feeding: Yes Y No N The please complete Change to nutritional support form			
Other energy sources and attach to CRF			
IV glucose: Yes Y No N 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			
— Insul <u>in ————————————————————————————————————</u>			
Insulin: Yes Y No N If yes Total units:			
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 No No 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: DDDDDDDDDDDDDDDDDDDDDDDDDDDDDDDDDDDD			

Day 1 - Physiology/Interventions



(from start to 23:59)

Physiology ————	Not recorded (NR)		Not recorded (NR)	
Lowest P/F ratio:		l [']			
PaO ₂ : kPa K mm	iHg(M) (NR)	Lowest Albumin:		g l ⁻¹ (NR)	
FiO ₂ :		Highest AST:		units I ⁻¹ (NR)	
P/F ratio on mechanical ventilation: Yes	Y No (N)	Highest ALP:		units Γ ¹ (NR)	
Lowest MAP: mmHg	or -	Highest ALT:		units Γ ¹ (NR)	
	or NR	Lowest platelets:		x10 ⁹ l ⁻¹ NR	
Lowest SBP/DBP:	mmHg	Highest bilirubin:		μmol ⁻¹ (NR)	
Lowest glucose: · mi	mol ⁻¹ (NR)	Highest creatinine:		µmol ⁻¹ (NR)	
Highest glucose: · m	mol ⁻¹ NR	Urine output:	r	nl NR	
— Glasgow Coma Score (GCS)					
Lowest total GCS:					
Eye opening response	Motor response		Verbal respo		
Spontaneous 4	Obeys commands	\times	Oriented	5	
To speech (3)	Localises to painf	ul stimuli 5	Confused	4	
To painful stimulation 2	Withdrawal to pai	nful stimuli (4)	Inappropriate	words (3)	
No response	Abnormal flexion	(3)	Incomprehens	ible sounds (2)	
Extends to painful stimuli 2 No response					
No response					
Pre-sedation value: Yes Y No	N			Not recorded: NR	
— Interventions —					
Vasoactives administered: Yes Y	No (N)				
If yes				≤5 µg kg ⁻¹ min ⁻¹	
Epinephrine: Yes (Y)	0.1 µg kg ⁻¹ min ⁻¹	Dopamine: Yes	Max. rate	>5 µg kg ⁻¹ min ⁻¹ M	
).1 μg kg ⁻¹ min ⁻¹ (U			>15 µg kg ⁻¹ min ⁻¹ U	
Norepinephrine: Yes Max. rate Solid μg kg ⁻¹ min ⁻¹ >0.1 μg kg ⁻¹ min ⁻¹ U Dobutamine: Yes Y					
Systemic antibacterials: Yes Y	lo (N	Systemic antif	ungals: Yes	Y No (N)	
If yes					
Prophylactic P Therapeutic T Prophylactic P Therapeutic T					
Committee Albert					
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) **Nutritional support** Route: Specify other: Subclavian Femoral PICC Other Jugular Parenteral Product: Total volume: ml Additives: Glutamine: Ν Fish oils: Yes No Yes No Ν Selenium: Yes No Ν (EN \mathbb{N} Р Enteral Nose Mouth Percutaneous Specify other: Stomach Duodenum Jejunum Other Total volume: ml Product: Total volume 'put back': Total volume of aspirates: No Ν Prokinetics: Exclusive oral feeding Change to nutritional support If yes, then please complete Change either to route/site/product Ν Change to nutritional support form Yes No or a change to exclusive oral feeding: and attach to CRF Other energy sources If yes ml IV glucose: mI [ml No

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: Voc V No Ni If was then please complete infectious apisodes form (nage 34)					

Adverse event related to trial treatment:	Yes Y No No No If yes, then please complete Safety monitoring form (page 38)
Completed by: (print name) Signature:	Pote completed D D M M Z 0 Y Y

Day 2 - Physiology/Interventions (from 00:00 to 23:59)





Physiology —	Not recorded (I	NR)		Not recorded (NR)	
Lowest P/F ratio:					
PaO ₂ : kPa K m	nmHg(M) (NR)	Lowest Albumin:		g I ⁻¹ (NR)	
FiO ₂ :		Highest AST:		units Γ ¹ (NR)	
P/F ratio on mechanical ventilation: Yes	Y No N	Highest ALP:		units I ⁻¹ (NR)	
Lowest MAP: mmHg		Highest ALT:		units I ⁻¹ NR	
	<u>or</u>	Lowest platelets:		x10 ⁹ l ⁻¹ NR	
Lowest SBP/DBP:	mmHg	Highest bilirubin:		μmol ⁻¹ (NR)	
Lowest glucose: mmol ⁻¹ NR		Highest creatinine:		µmol ⁻¹ (NR)	
Highest glucose:	mmol ⁻¹ (NR)	Urine output:		ml (NR)	
— Glasgow Coma Score (GCS)				
Lowest total GCS:	,				
Eye opening response	Motor response		Verbal respo	onse	
Spontaneous 4	Obeys commands	6	Oriented	(5)	
To speech 3	Localises to painfo	ul stimuli 5	Confused	4	
To painful stimulation	Withdrawal to pair	nful stimuli 4		words 3	
		\times	Inappropriate	\times	
No response 1 Abnormal flexion 3 Incomprehensible sounds 2				sible 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	140			≤5 µg kg ⁻¹ min ⁻¹ (L	
Max. rate	≤0.1 µg kg ⁻¹ min ⁻¹ (Max. rate		
Epinephrine: Yes (Y)	>0.1 µg kg ⁻¹ min ⁻¹	Dopamine: Yes	Y	>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	Dobutomino: V			
Norepinephrine: Yes Y					
Systemic antibacterials: Yes Y No N Systemic antifungals: Yes Y No N					
If yes If yes Prophylactic □ Therapeutic □ Therapeutic □					
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) calor **Nutritional support** Route: Specify other: Jugular Subclavian Femoral PICC Other Parenteral Product: Total volume: ml Additives: Glutamine: Fish oils: No Ν Yes Ν Selenium: Nose Ν Mouth Р Percutaneous Enteral Specify other: Stomach Duodenum Jejunum Other Total volume: ml Product: Total volume 'put back': ml ml Total volume of aspirates: Prokinetics: Yes No Ν Exclusive oral feeding Change to nutritional support If yes, then please complete Change either to route/site/product Change to nutritional support form Yes No or a change to exclusive oral feeding: and attach to CRF Other energy sources If yes IV glucose: Yes No Propofol: If yes 1% ml 2% ml Yes No Ν ml Oral feed: Yes No If yes Product: Total: calories – Insulin Insulin: Yes No Ν Total units: - Stools Bowels open: Yes No Unable to assess Hard and formed Soft and formed Loose and unformed Liquid - Infectious episodes and Adverse events New infectious episode: If yes, then please complete Infectious episodes form (page 34) Yes No Adverse event related If yes, then please complete Safety monitoring form (page 38) Ν Yes No to trial treatment:

Date completed:

Completed by: (print name)

Signature:

Day 3 — Physiology/Interventions (from 00:00 to 23:59)



Physiology Not recorded	(NID) Not recorded (NID)				
Lowest P/F ratio:					
PaO ₂ : kPa k mmHg M NR	Lowest Albumin: g l ⁻¹ (NR)				
FiO ₂ :	Highest AST: units Γ¹ (NR)				
P/F ratio on mechanical ventilation: Yes (Y) No (N)	Highest ALP: units I ⁻¹ NR				
Lowest MAP: mmHg or	Highest ALT: units Γ ¹ NR				
NR)	Lowest platelets: x10 ⁹ Г ¹ NR				
Lowest SBP/DBP: mmHg	Highest bilirubin: . µmol ⁻¹ NR				
Lowest glucose: . mmol ⁻¹ NR	Highest creatinine: µmol ⁻¹ NR				
Highest glucose: . mmol ⁻¹ NR	Urine output: ml NR				
Glasgow Coma Score (GCS)					
Lowest total GCS:					
Eye opening response Motor response					
Spontaneous 4 Obeys command	> Official >				
To speech (3) Localises to pain	ful stimuli 5 Confused 4				
To painful stimulation 2 Withdrawal to pa	inful stimuli (4) Inappropriate words (3)				
No response 1 Abnormal flexion	3 Incomprehensible sounds 2				
Evtende to poinful ctimuli					
No response					
Tes Y No N					
Interventions —					
Vasoactives administered: Yes (Y) No (N)					
If yes Max. rate ≤0.1 µg kg ⁻¹ min ⁻¹	≤5 µg kg ⁻¹ min ⁻¹ (L)				
Epinephrine: Yes (Y)	Dopamine: Yes Y Max. rate >5 µg kg ⁻¹ min ⁻¹ M				
>0.1 µg kg ⁻¹ min ⁻¹	>15 µg kg ⁻¹ min ⁻¹ (U)				
Max. rate ≤0.1 µg kg ⁻¹ min ⁻¹					
Norepinephrine: Yes Y Max. rate < 0.1 µg kg ⁻¹ min ⁻¹ Dobutamine: Yes Y >0.1 µg kg ⁻¹ min ⁻¹					
Systemic antibacterials: Yes Y No N Systemic antifungals: Yes Y No N Systemic antifungals: Yes Y No N N					
If yes If yes Prophylactic □ Therapeutic □ Therapeutic □					
O-market dham					
Completed by: (print name)					
Signature:	Date completed:				

Day 4 - Nutritional support (from 00:00 to 23:59) **Nutritional support** Route: Specify other: Jugular Subclavian Femoral PICC Other Parenteral Product: Total volume: ml Additives: Glutamine: No Ν Fish oils: Yes No Yes Selenium: Yes No (EN Ν Р Enteral Nose Mouth \mathbb{M} Percutaneous Specify other: Stomach Duodenum Jejunum Other Total volume: ml Product: Total volume 'put back': Total volume of aspirates: Prokinetics: Exclusive oral feeding Change to nutritional support If yes, then please complete Change either to route/site/product Yes No Change to nutritional support form or a change to exclusive oral feeding: and attach to CRF Other energy sources If yes IV glucose: ml [ml ml Yes No Ν If yes 1% 2% ml Propofol: Yes No ml Oral feed: If yes Product: Total: Yes No calories – Insulin Ν Total units: IU Yes No If yes Insulin: - Stools Bowels open: Yes No Ν Unable to assess Hard and formed Soft and formed (Loose and unformed Liquid - Infectious episodes and Adverse events New infectious episode: If yes, then please complete Infectious episodes form (page 34) No

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:

Day 4 - Physiology/Interventions (from 00:00 to 23:59)



-1 · 1					
Physiology — Lowest P/F ratio:	Not recorded (NR)		Not recorded (NR)	
	nHg M NR	Lowest Albumin:		g Γ ¹ NR	
FiO ₂ :		Highest AST:		units I ⁻¹ NR	
P/F ratio on mechanical ventilation: Yes (Y No (N)	Highest ALP:		units I ⁻¹	
		Highest ALT:		units I ⁻¹ NR	
Lowest MAP: mmHg	or NR	Lowest platelets:		x10 ⁹ l ⁻¹ NR	
Lowest SBP/DBP:	mmHg	Highest bilirubin:	-	µmol ⁻¹ NR	
Lowest glucose: r	nmol ⁻¹ (NR)	Highest creatinine		µmol ⁻¹ NR	
Highest glucose: n	nmol ⁻¹ NR	Urine output:		ml NR	
Glasgow Coma Score (GCS)					
Lowest total GCS:					
F	Matar range		Varbal raana		
Eye opening response Spontaneous	Motor response Obeys commands	6	Verbal responsible Oriented	onse	
Spontaneous 4 To speech 3	Localises to painf	\times	Confused	4	
To painful stimulation 2	Withdrawal to pair	nful stimuli 4	Inappropriate	words 3	
Abnormal flavion			sible sounds 2		
Incomprehensible sounds				sible sounds	
Extends to painful stimuli No response 1 No response					
Pro codation value:					
Yes Y No Interventions	N			THOUT TOOG TAGE.	
Interventions —					
Vasoactives administered: Yes Y	No (N)				
	0.1 μg kg ⁻¹ min ⁻¹			≤5 µg kg ⁻¹ min ⁻¹ (L	
Epinephrine: Yes (Y)	0.1 µg kg ⁻¹ min ⁻¹	Dopamine: Yes	Max. rate	→ >5 μg kg ⁻¹ min ⁻¹ (M)	
	0.1 pg kg 11			>15 μg kg ⁻¹ min ⁻¹ U	
Max. rate ≤	:0.1 μg kg ⁻¹ min ⁻¹				
Norepinephrine: Yes (Y) >0.1 µg kg ⁻¹ min ⁻¹ U Dobutamine: Yes (Y)					
Systemic antibacterials: Yes Y No N Systemic antifungals: Yes Y No N					
If yes If yes Prophylactic					
Completed by					
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) calor **Nutritional support** Specify other: Jugular Subclavian Femoral PICC Other Parenteral Product: Total volume: Additives: Glutamine: Yes No Ν Fish oils: Yes No Selenium: Yes No Ν Р Enteral Nose Mouth \mathbb{M} Percutaneous Specify other: Jejunum Stomach Duodenum Other Total volume: ml Product: Total volume 'put back': Total volume of aspirates: Ν Prokinetics: Exclusive oral feeding Change to nutritional support If yes, then please complete Change either to route/site/product Change to nutritional support form Yes No or a change to exclusive oral feeding: and attach to CRF Other energy sources If yes IV glucose: ml [ml Yes No If yes 1% 2% Propofol: Yes No ml Oral feed: If yes Product: Total: calories - Insulin Insulin: Yes Total units:

St	ools —	
	Bowels open: Yes Y No N Unable to assess U	
Har	d and formed 1 Soft and formed 2 Loose and unformed 3 Liquid 4	
In	fectious episodes and Adverse events ————————————————————————————————————	

Completed by:									
Signature:	Date completed:	D	D	М	М	2	0	Υ	Υ

Day 5 - Physiology/Interventions (from 00:00 to 23:59)



Physiology —	Not recorded (NID)		Not recorded (NR)		
Lowest P/F ratio:	Not recorded (l [′]				
PaO ₂ : kPa K mr	mHg(M) (NR)	Lowest Albumin:	• g l ⁻¹	\sim		
FiO ₂ :		Highest AST:		units I ⁻¹ (NR)		
P/F ratio on mechanical ventilation: Yes (Y No (N)	Highest ALP:	units			
L SUUS STANAR		Highest ALT:	u	nits I ⁻¹ NR		
Lowest MAP: mmHg	<u>or</u>	Lowest platelets:	x1	0 ⁹ Γ ¹ NR		
Lowest SBP/DBP:	mmHg	Highest bilirubin:		µmol ⁻¹ (NR)		
Lowest glucose: . n	nmol ⁻¹ NR	Highest creatinine:		umol ⁻¹ (NR)		
Highest glucose: n	nmol ⁻¹ NR	Urine output:	ml	NR		
Glasgow Coma Score (GCS)						
Lowest total GCS:						
Eye opening response	Motor response		Verbal response			
Spontaneous 4	Obeys commands	\times	Oriented	5		
To speech (3)	Localises to painfe	ul stimuli 5	Confused	(4)		
To painful stimulation (2)	Withdrawal to pair	nful stimuli (4)	Inappropriate words	(3)		
No response	Abnormal flexion	3				
No response		\times	Incomprehensible so	bunds		
	Extends to painful	stimuli 2	No response			
	No response					
Pre-sedation value: Yes Y No	N		Not	recorded: NR		
Interventions —						
Vasoactives administered: Yes Y	No (N					
If yes			<5.1	ug kg ⁻¹ min ⁻¹ (L		
May rate	ε0.1 μg kg ⁻¹ min ⁻¹		May rate	\sim		
Epinephrine: Yes (Y)	∙0.1 μg kg ⁻¹ min ⁻¹ ∪	Dopamine: Yes	>5 I	ug kg ⁻¹ min ⁻¹ (M)		
	0.1 µg kg 11iii1		>15	i μg kg ⁻¹ min ⁻¹ U		
Norepinephrine: Yes (Y) Max. rate	≤0.1 µg kg ⁻¹ min ⁻¹	Debutenie v				
	>0.1 μg kg ⁻¹ min ⁻¹ Ū	Dobutamine: Y	es			
Systemic antibacterials: Yes Y	No (N	Systemic antil	fungals: Yes Y	No (N)		
	140	•	unguis.	NO N		
If yes Prophylactic P Therapeutic T 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) - Nutritional support Specify other: Parenteral (PN Jugular Subclavian (S Femoral (F PICC (P Other Product: Total volume: 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 Jeiunum J Other Stomach S Duodenum D Jeiunum J Other Stomach S Duodenum D Jeiunum J Other S Duodenum D Jeiunum D Specify other:
Product: Total volume: ml
Total volume of aspirates: ml Total volume 'put back': ml
Exclusive oral feeding Prokinetics: Yes Y No N
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 If yes
IV glucose: Yes Y No N ml ml ml ml ml
Propofol: Yes Y No N If yes 1% ml 2% ml
Oral feed: Yes Y No N If yes Product: Total: Total: Calories
Insulin —
Insulin: Yes Y No No N If yes Total units:
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 No No If yes, then please complete Infectious episodes form (page 34)
Adverse event related to trial treatment: Yes Y No
Completed by:
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)



Physiology —	Not recorded (NR)	1	Not recorded (NR)
Lowest P/F ratio: PaO ₂ : kPa K mn	nHg M NR	Lowest Albumin:	· g l ⁻¹	(NR)
	" IS (M)	Highest AST:		ts I ⁻¹ (NR)
FiO ₂ :		Highest ALP:	units I ⁻¹	(NR)
P/F ratio on mechanical ventilation: Yes	Y No (N)			\sim 1
Lowest MAP: mmHg	<u>or</u>	Highest ALT:	units	\sim
Lowest SBP/DBP:	mmHg	Lowest platelets:	x10 ⁹ l ⁻	1 (NR)
		Highest bilirubin:	μr	mol ⁻¹ (NR)
Lowest glucose: · m	mol ⁻¹ (NR)	Highest creatinine:	μπο	l ⁻¹ NR
Highest glucose:	imol ⁻¹ NR	Urine output:	ml	NR
Glasgow Coma Score (GCS)				
Lowest total GCS:				
Eye opening response	Motor response		Verbal response	
Spontaneous 4	Obeys commands	\times	Oriented	5
To speech 3	Localises to painfe	ul stimuli 5	Confused	(4)
To painful stimulation 2	Withdrawal to pair	nful stimuli (4)	Inappropriate words	(3)
No response	Abnormal flexion	(3)	Incomprehensible sound	ds (2)
	Extends to painful	stimuli (2)	No response	
	No response		No response	
Pre-sedation value: Yes Y No	N		Not reco	orded: NR
Interventions				
Vasoactives administered: Yes Y	No N			
If yes	(≤5 µg k	g ⁻¹ min ⁻¹ (L)
Epinephrine: Yes (Y)	0.1 µg kg ⁻¹ min ⁻¹	Dopamine: Yes	Max. rate >5 μg k	g ⁻¹ min ⁻¹ M
>	0.1 µg kg ⁻¹ min ⁻¹			kg ⁻¹ min ⁻¹ U
			> 10 μg	Ng IIIIII
Norepinephrine: Yes (Y)	0.1 μg kg ⁻¹ min ⁻¹	Dobutamine: Ye	es (Y)	
<u> </u>	0.1 μg kg ⁻¹ min ⁻¹ (
	. (2)		. [.,	
	No (N)	Systemic antif	ungals: Yes Y N	o (N)
If yes Prophylactic P Therapeutic	T	If yes Prophyla	ctic P Therapeutic	T
Completed by: (print name)				
Signature:		Date completed:	D D M M 2	2 0 Y Y



— Date and e	stimated 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
Enteral EN	Product: Total volume: ml Additives: Glutamine: Yes Y No N Fish oils: Yes Y No N Selenium: Yes Y No N Nose N Mouth M Percutaneous P Stomach S Duodenum D Jejunum J Other O Product: Total volume: ml Total volume of aspirates: ml Total volume 'put back': ml
Exclusive oral feeding	Prokinetics: Yes Y No N
Comments	
Completed by: (print name) Signature:	Date completed: DDDMM M 2 0 Y Y

At discharge from your critical care unit



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						
*Route: E=Enteral (exclusive), P=Parenteral (exclusive), O=Oral feeding (exclusive), EP=Enteral & Parenteral,						
*Route: *P=Enteral (exclusive), P=Parenteral (exclusive), V=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) Systemic antifungals: Yes (Y) No (N)						
If yes						
Prophylactic P Therapeutic T 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 Stage II II Stage IV IV No NR No 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: 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						
Signature: Date completed: D D M M D 2 0 Y Y						



Infectious episodes
(from randomisation onwards to discharge from your critical care unit)

	ly suspected or confi	rmed 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		
	Tes NO N		
	Yes (Y) No (N)		
	Yes (Y) No (N)		
	Yes (Y) No (N)	D D M M 2 0 Y Y	
Clinical diag		rmed infections (other) Start of treatment date:	Organism(s):
Clinical diag			Organism(s):
	Yes (Y) No	N D D M M 2 0 Y Treatment:	Y
		Treatment.	
	Yes (Y) No	N D D M M 2 0 Y	Y
¹ Clinical dia	gnosis: B=Bloodstream ii	nfection, C=CVC infection, =Infectious co	olitis,
∪=∪tner va	Scular catheter intection, i	P=Pneumonia, S=Surgical site infection, U	-оппагу tract infection
² Confirmed	= laboratory/microbiologi	cal confirmation	
Complete	ed by:		
(print na	me)		
Cimmotum			

At discharge from your hospital



	location within your hospital (from discharge from your critic	al care unit) —
	om your critical care unit ®	
Lo	Location*: Start date: Start time: (24-ho	ur clock)
	D D M M 2 0 Y Y H H : M	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
*Lo	Location: A=Acute Admissions Unit (or equivalent), W=Ward, I=ICU or ICU/HDU,	
	H=HDU, E=Emergency Department, T=Theatre	
— Exclusive or	oral feeding —	
	eding commenced since discharge from your critical care unit:	
If yes		
Date exclusive oral	al feeding commenced:	
Acute hospi	pital discharge ————————————————————————————————————	
Acute hospital dis	discharge status (from your hospital): Alive A Dead D	
If alive	If dead	
Date of discharge:		2 0 Y Y
Discharge location		
Districting location	Home H Time of death: H H S M	M
	Nursing Home	
	Transfer to other acute hospital T	ospital:
	Other Status: Alive (A) Dead (I	
	Specify Date: Date	
	Date: D D M M / 2	0
	Note: Please obtain Retrospective consent prior to dischar	ge
— Comments		
Completed by:	v:	
(print name)		
Signature:	Date completed:	2 0 Y Y

Safety monitoring (SOP 013)

(known adverse events from randomisation ® 30 days)



Adverse events (specified) Severity ¹		art d	ato								Start	time:	(2/	-hour	clock)	Relate	ed.
Abdominal distension:	. J.			M	M]/	2	0	Υ	Υ	Н	Н	:	M	M		
Abdominal pain:	D	Г		M	M	1	2	0	Υ	Υ	Н	Н	 	M	M		
Electrolyte disturbance:	D	С		M	M		2	0	Υ	Υ	Н	Н	-	M	M		
Haemo-pneumothorax:	D	Г		М	М	1	2	0	Υ	Υ	Н	Н	-	M	M		ĺ
Hepatomegaly:	D	Г		М	М	ĺ	2	0	Υ	Υ	Н	Н	-	M	M		ĺ
Hyperosmolar syndrome:	D	Г		М	M		2	0	Υ	Υ	Н	Н	Ī:	M	M		آ
Hypersensitivity reaction (anaphylactic reaction):	D	D		М	М	M	2	0	Υ	Υ	Н	Н	Ī:	M	М		٦
Hypoglycaemia:	D			M	М	V	2	0	Υ	Υ	Н	Н	Ī:	M	М		Ī
Ischaemic bowel:	D	С		М	М		2	0	Υ	Υ	Н	Н	<u></u>	M	M		j
Jaundice:	D			М	М		2	0	Υ	Υ	Н	Н]:	M	M		j
Nausea requiring treatment:	D			M	М		2	0	Υ	Υ	Н	Н	<u> </u>	M	M		ĺ
Pneumothorax:	D			М	M		2	0	Υ	Υ	Н	Н]:	M	M		j
Raised liver enzymes:	D	Г		М	М		2	0	Υ	Υ	Н	Н] :	M	M		
Regurgitation/aspiration:	D	Г		М	M	V	2	0	Υ	Υ	Н	Н	:	M	M		Ī
Vascular catheter related infection:	D	Г		M	М		2	0	Υ	Υ	Н	Н] :	M	M		
Vomiting:	D	Г		М	M		2	0	Υ	Υ	Н	Н] :	M	M		
Adverse events (other) —																	_
Adverse event: Severity ¹ :	Sta	art d	ate:	:							Start	time:	(24	-hour	clock)	Relate	e
	D	D		М	M	И	2	0	Υ	Υ	Н	Н]:	M	М		
	D	D		М	M		2	0	Υ	Υ	Н	Н]:	M	М		
	D	D		М	M	И	2	0	Υ	Υ	Н	Н	:	M	M		
	D	D	$\bar{\mathbb{Z}}$	М	M	Й	2	0	Υ	Υ	Н	Н	Ī:	M	М		
	D	D	1	М	М	Й	2	0	Υ	Υ	Н	Н] :	M	М		ĺ
	D	Ь	ī,	М	М	, . 1 /	2	0	Υ	Y	Н	Н	Ī.	M	М		ĺ

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

Completed by:									
Signature:	Date completed:	D	D	М	M	2	0	Υ	Υ

Retrospective consent



 Retrospective co 	nsent —
Regained mental capacity	Yes Y No N
Retrospective consent:	Obtained
	Part-obtained P Date: D D M M 2 0 Y Y
	Refused
	Not sought N
If part-obtained/not soug	ght
Details:	

Comments -		

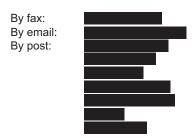
Completed by: (print name)								
Signature:	Date completed:	D	М	М	2	0	Υ	Υ

Death notification



— Death ——	
Date of death:	

If completed, return to ICNARC CTU



Comments —		

Completed by: (print name)								
Signature:	Date completed:	D	М	M	2	0	Υ	Y

Withdrawal of consent/agreement



— Withdrawal of consent/agreement —						
Date of withdrawal:						
Reason (if available):						
Consent withdrawn by:	Patient 1 Personal Consultee 2 Professional Consultee 3					

If completed, return to ICNARC CTU

By fax:
By email:
By post:

Comments			

Completed by:							
Signature:	Date completed:	D D	М	2	0	Υ	Υ