Trial registered on ANZCTR

Trial ID	ACTRN12614000476639
Ethics application status	Approved
Date submitted	17/04/2014
Date registered	8/05/2014
Type of registration	Prospectively registered

Titles & IDs

Public title	Effects of normocaloric vs. hypocaloric enteral nutrition on whole-body protein turnover in critically ill patients
Scientific title	Effects of normocaloric vs. hypocaloric enteral nutrition on whole-body protein turnover in critically ill patients
Secondary ID [1]	Nil
Universal Trial Number (UTN)	
Trial acronym	

Health condition

Health condition(s) or problem(s) studied:

Critical illness

Condition category	Condition code
Diet and Nutrition	Other diet and nutrition disorders
Metabolic and Endocrine	Other metabolic disorders

Intervention/exposure

Study type	Interventional
Description of intervention(s) / exposure	Critically ill patients from a medical/surgical adult ICU who are on stable, normocaloric, enteral nutrition via nasogastric tube/gastrostomy/jejunostomy are studied twice on consecutive days. Indirect calorimetry is performed to determine energy expenditure. Enteral nutrition is given at 100% of energy expenditure (normocaloric) for 24 hrs on one day, and at 50% of energy expenditure (hypocaloric) for 24 hrs on the other, in randomised order. Measurements of whole-body protein kinetics are made during the last 2 hrs of each 24 hr study period. Intravenous infusions of stable isotope labeled phenylalanine and tyrosine are administered to measure whole-body protein turnover. A different stable isotope labeled phenylalanine tracer is administered enterally during the last 8 hrs of each 24 hr study period to enable calculation of dietary contribution to whole-body protein turnover. Parameters of steady-state whole body protein turnover are calculated from arterial plasma enrichments of isotope labeled phenylalanine and tyrosine tracers.
Intervention code [1]	Treatment: Other
Comparator / control treatment	Patients are studied twice on consecutive days and serve as their own controls. Normocaloric nutrition is considered the control and hypocolaric nutrition the intervention treatment.
Control group	Active

Outcomes

Primary outcome [1]

	Whole body net protein balance Whole-body protein breakdown and synthesis is calculated from arterial plasma enrichments of isotope labeled phenylalanine and tyrosine tracers. The arithmetic difference of breakdown and synthesis is the net protein balance which is the main outcome. Intermediary calculations are also reported for clarity.
Timepoint [1]	Parameters of whole body protein turnover are measured 22 hrs post initiation of normocaloric enteral nutrition and 22 hrs post initiation of hypocaloric enteral nutrition
Secondary outcome [1]	Splanchnic extraction fraction of dietary phenylalanine is calculated from arterial plasma enrichments of isotope labeled phenylalanine and tyrosine tracers.
Timepoint [1]	Splanchnic extraction fraction of dietary phenylalanine is measured 22 hrs post initiation of normocaloric enteral nutrition and 22 hrs post initiation of hypocaloric enteral nutrition
Secondary outcome [2]	Plasma amino acid profile
Timepoint [2]	Plasma amino acid profile is measured before intervention, 22 hrs post initiation of normocaloric enteral nutrition, and 22 hrs post initiation of hypocaloric enteral nutrition

Eligibility

Key inclusion criteria	Critically ill patients on stable, normocaloric, enteral nutrition nutrition via nasogastric feeding tube/gastrostomy/jejunostomy
Minimum age	18 Years
Maximum age	No limit
Gender	Both males and females
Can healthy volunteers participate?	No
Key exclusion criteria	Blood transfusion during study period, intolerance of enteral nutrition at time of recruitment

Study design

Purpose of the study	Treatment
Allocation to intervention	Randomised controlled trial
Procedure for enrolling a subject and allocating the treatment (allocation concealment procedures)	Patients are recruited from ICU clientele as available. Randomisation to order of treatment (first normocaloric, then hypocaloric vs. first hypocaloric, then normocaloric) is done by sealed opaque envelope drawing in blocks.
Methods used to generate the sequence in which subjects will be randomised (sequence generation)	
Masking / blinding	Open (masking not used)
Who is / are masked / blinded?	
Intervention assignment	Crossover
Other design features	A crossover design is used because the outcome measures are presumably subject to temporal variation, due to confounding factors such as the natural course of disease, complications, and therapeutic interventions.
Phase	Not Applicable
Type of endpoint(s)	Pharmacokinetics

Recruitment

Anticipated date of first participant enrolment	1/04/2016
Actual date of first participant enrolment	
Anticipated date last participant enrolled	
Actual date last participant enrolled	
Target sample size	12
Actual sample size	
Recruitment status	Not yet recruiting

Recruitment outside Australia

Country [1]	Sweden
State/province [1]	

Funding & Sponsors

Funding source category [1]	Government body
Name [1]	Regional Agreement on Medical Training and Clinical Research (ALF) between Stockholm County Council and Karolinska Institutet
Address [1]	Stockholm County Council Stockholms lans landsting Box 22550 104 22 Stockholm
Country [1]	Sweden
Primary sponsor type	Individual
Name	Prof Olav Rooyackers
Address	Karolinska Institutet Inst. for klinisk vetenskap, intervention och teknik Enheten for anestesi Karolinska Universitetssjukhuset, Huddinge, K32 141 86 Stockholm
Country	Sweden
Secondary sponsor category [1]	None
Name [1]	
Address [1]	
Country [1]	

Ethics approval

Ethics application status	Approved
Ethics committee name [1]	Regionala etikprovningsnamnden i Stockholm
Ethics committee address [1]	Box 289 (Nobels vag 12 A) 171 77 Stockholm
Ethics committee country [1]	Sweden
Date submitted for ethics approval [1]	30/04/2014
Approval date [1]	17/02/2016
Ethics approval number [1]	2016/76-31/4

Summary

Brief summary	Critically ill patients suffer from catabolism, i.e. protein loss, which may contribute to complications such as muscle weakness, protracted ventilator treatment, and delayed recovery. Appropriate feeding may alleviate catabolism, but ideal feeding strategies are controversial, partly because the underlying physiology is poorly understood. An earlier study (Berg A et al. (2013), Crit Care 17(4): R158) has shown that protein catabolism is reduced when a higher dose of nutrition is given by the intravenous route. We now investigate the effect of a full dose vs. lower dose nutrition regimen where feeding is given via a nasogastric feeding tube, gastrostomy or jejunostomy. Using stable isotope techniques, we measure whether whole-body protein turnover is affected by the dose of nutrition.
Trial website	
Trial related presentations / publications	
Public notes	

Contacts

Principal investigator

Name	Prof Olav Rooyackers
Address	Karolinska Institutet Inst. for klinisk vetenskap, intervention och teknik Enheten for anestesi Karolinska Universitetssjukhuset, Huddinge, K32 141 86 Stockholm
Country	Sweden
Phone	+46-8-58580553
Fax	
Email	olav.rooyackers@ki.se

Contact person for public queries

Name	Prof Olav Rooyackers
Address	Karolinska Institutet Inst. for klinisk vetenskap, intervention och teknik Enheten for anestesi Karolinska Universitetssjukhuset, Huddinge, K32 141 86 Stockholm
Country	Sweden
Phone	+46-8-58580553
Fax	
Email	olav.rooyackers@ki.se

Contact person for scientific queries

Name	Prof Olav Rooyackers
Address	Karolinska Institutet Inst. for klinisk vetenskap, intervention och teknik Enheten for anestesi Karolinska Universitetssjukhuset, Huddinge, K32 141 86 Stockholm
Country	Sweden
Phone	+46-8-58580553
Fax	
Email	olav.rooyackers@ki.se

< BACK

Web design by G Squared

Copyright © Australian New Zealand Clinical Trials Registry. All rights reserved.