**Trial registered on ANZCTR**

<table>
<thead>
<tr>
<th><strong>Trial ID</strong></th>
<th>ACTRN12614000476639</th>
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</thead>
<tbody>
<tr>
<td><strong>Ethics application status</strong></td>
<td>Approved</td>
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<tr>
<td><strong>Date submitted</strong></td>
<td>17/04/2014</td>
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<tr>
<td><strong>Date registered</strong></td>
<td>8/05/2014</td>
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<tr>
<td><strong>Type of registration</strong></td>
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**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**

- Diet and Nutrition
- Metabolic and Endocrine

**Condition code**

- Other diet and nutrition disorders
- Other metabolic disorders

**Intervention/exposure**

**Study type**

- Intervenional

**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.

**Comparator / control treatment**

- Patients are studied twice on consecutive days and serve as their own controls. Normocaloric nutrition is considered the control and hypocaloric nutrition the intervention treatment.

**Control group**

- Active

**Intervention code [1]**

- Treatment: Other

**Outcomes**

**Primary outcome [1]**

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https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=366000&isReview...  2016-03-14
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 via nasogastric feeding tube/gastrostomy/jejunosomy

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) Open (masking not used)

Masking / blinding Open (masking not used)

Who is / are masked / blinded? 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

<table>
<thead>
<tr>
<th>Funding source category [1]</th>
<th>Government body</th>
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<tr>
<td>Name [1]</td>
<td>Regional Agreement on Medical Training and Clinical Research (ALF) between Stockholm County Council and Karolinska Institutet</td>
</tr>
</tbody>
</table>
| 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 |
| Secondary sponsor category [1] | None |
| Name [1]                   | None |
| Address [1]                | None |
| Country [1]                | None |

Ethics approval

<table>
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<tr>
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<tr>
<td>Ethics committee name [1]</td>
<td>Regionala etikprövningsnämnden i Stockholm</td>
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| 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

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<thead>
<tr>
<th>Name</th>
<th>Prof Olav Rooyackers</th>
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Contact person for public queries

https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=366000&isReview... 2016-03-14
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