# The effect of standard or higher protein feeding on indicator amino acid oxidation in ICU patients

Published: 29-06-2023 Last updated: 14-12-2024

To assess the effect of enteral feeding with higher protein content compared to standard protein content on indicator amino acid oxidation in ICU patients.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

# Summary

### ID

NL-OMON53266

**Source** ToetsingOnline

Brief title

### Condition

Other condition

#### Synonym

Protein requirement; Need for protein

#### **Health condition**

Eiwitbehoefte

#### **Research involving** Human

### **Sponsors and support**

**Primary sponsor:** Universiteit Maastricht **Source(s) of monetary or material Support:** Ministerie van OC&W

### Intervention

Keyword: Critical illness, Intensive Care Unit, Protein requirement

### **Outcome measures**

#### **Primary outcome**

The primary endpoint is indicator amino acid oxidation after enteral feeding

with a standard or higher protein content, determined using the Indicator Amino

Acid Oxidation (IAAO) method by measuring 13CO2 enrichment in expired breath

and enrichment of L-[1-13C]-phenylalanine in plasma and urine.

### Secondary outcome

To determine carbon dioxide production, 13CO2 production, plasma and urine

L-[1-13C]-phenylalanine enrichments, plasma phenylalanine concentration, and

fecal output and protein content in ICU patients when applying the IAAO

technique.

# **Study description**

#### **Background summary**

While protein administration guidelines for critical care are available from international organizations such as ASPEN and ESPEN, they vary greatly in their recommended dose and are based on relatively low-quality evidence. The Indicator Amino Acid Oxidation (IAAO) technique has been developed as a more practical and non-invasive tool to assess protein metabolism that can be used in vulnerable populations. Application of the IAAO technique in patients admitted to the Intensive Care Unit (ICU) enables to better investigate optimal protein feeding during critical illness.

### **Study objective**

To assess the effect of enteral feeding with higher protein content compared to standard protein content on indicator amino acid oxidation in ICU patients.

### Study design

Randomized, counterbalanced, cross-over trial.

#### Intervention

Subjects will undergo two test days in randomized order during which they receive either enteral feeding according to a standard protein dose (1.3 g/kg/d) or a higher protein dose (2.0 g/kg/d). Continuous feeding of L-[1-13C]-phenylalanine combined with breath, urine, fecal and blood samples will be applied to assess indicator amino acid oxidation.

#### Study burden and risks

The overall risk of the study is negligible. The current study compares the effect of two nutritional compositions, that fall within the recommendations of international guidelines on ICU nutrition, on protein metabolism following ICU admission. As muscle wasting and increased protein requirements occur especially during the early phase of critical illness, the intervention has to be initiated at this stage. To avoid overfeeding in the early phase of critical illness, full enteral nutrition is provided after three days of gradual increase of intake. Sampling of breath, urine, feces and plasma does not bring additional risks for this population. Our department has an extensive background in amino acid stable isotope methodology, assessment of 13CO2 enrichment in expired breath samples, and assessment of carbon dioxide production by indirect calorimetry. Since no associated risks are involved for either of the interventions, and there is potential to improve care for ICU patients if the study is able to show a benefit of one treatment over the other, we believe it is both ethical and justified to perform the study in this patient group.

# Contacts

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# **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age

Adults (18-64 years) Elderly (65 years and older)

### **Inclusion criteria**

- >= 18 years old
- Unplanned admission to the ICU
- Mechanically ventilated
- Start of enteral nutrition within 2 days of intubation
- >= 3 days on enteral nutrition
- Expected remaining ICU stay on mechanical ventilation of >= 2 days

# **Exclusion criteria**

 Contra-indication for enteral nutrition at the discretion of the treating physician
Feeding intolerance during incremental feeding protocol
Moribund or withholding of treatment
On extracorporeal membrane oxygenation (ECMO)
Presence of chest drains, pneumothorax, tracheoesophageal fistula or subcutaneous emphysema
Kidney failure AND a \*no dialysis\*-code on admission
Hepatic encephalopathy (West Haven criteria 3-4)
BMI < 18 kg/m2</li>

# Study design

# Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	08-11-2023
Enrollment:	8
Туре:	Actual

# **Ethics review**

Approved WMO	
Date:	29-06-2023
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

# **Study registrations**

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

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# In other registers

# Register

ССМО

ID NL84098.000.23