# Gastrointestinal tolerance in ICU patients after administration of an energy and protein enriched peptide formula as compared to an isocaloric standard tube feed

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The objective of this study is to compare gastrointestinal tolerance in ICU patients during administration of an upgraded peptide based tube feed product to an isocaloric standard tube feed during a period of maximal two weeks.

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON45321

**Source**
ToetsingOnline

**Brief title**
Gastrointestinal tolerance of a peptide tube feed in ICU patients

### Condition

- Other condition

**Synonym**
gastrointestinal intolerance in critically ill patients

**Health condition**

Het voordoen van tolerantieproblemen bij sondevoeding

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Nutricia
**Source(s) of monetary or material Support:** Nutricia Research B.V. Nederland

## Intervention

**Keyword:** Gastrointestinal tolerance, ICU patients, tube feed

## Outcome measures

### Primary outcome

No primary outcome is defined, because gastrointestinal tolerance cannot be

described by one single symptom (Reintam Blaser 2014).

The main outcome parameter is gastrointestinal tolerance measured by:

- Time period till first defecation since start study product

- Defecation frequency

- Defecation consistency based on Bristol Stool Form Scale (BSFS)

- Incidence of diarrhoea, constipation and vomiting

- Daily gastric residual volume

- Daily intake of study product

- Daily energy and protein intake from study product

### Secondary outcome

Other parameters in this study are:

- Faecal weight and consistency based on King*s Stool Chart

- Duration of ICU stay

- Length of hospital stay

- Ventilator free days

- ICU, hospital and 28-day mortality

- SOFA (sub) score(s)

- Gastric pH

- Serum concentration of amino acids

- Protein absorption

# Study description

### Background summary

Feeding the patients on an intensive care unit (ICU) is challenging. Most ICU patients are sedated and need to be tube fed. Medications and sedation reduce the absorption and tolerance to tube feed, leading to stomach and intestinal complaints like diarrhoea and poor feed absorption. This results in lower intake of the tube feed, weight loss (especially muscle) and a worsened clinical outcome.
Tube feeds normally used at the ICU are with intact nutrients like intact protein. Peptide feeds are recommended for patients with persistent diarrhoea. Nutricia has a peptide feed on the market that is being used in ICU patients for more than 15 years. The energy and protein content of this peptide feed is increased to meet the new nutritional recommendations for feeding ICU patients. Additionally, a different peptide source is being used which might give less stomach and intestine complaints.
The purpose of this study is to compare the gastrointestinal tolerance of this adapted peptide feed to a standard isocaloric tube feed after administration to ICU patients.Patients will received the peptide feed or the standard tube feed for up to 2 weeks. This study will give more insight in the tolerance of the adapted peptide feed.

### Study objective

The objective of this study is to compare gastrointestinal tolerance in ICU patients during administration of an upgraded peptide based tube feed product to an isocaloric standard tube feed during a period of maximal two weeks.

### Study design

This is a randomised, controlled, double blind, parallel-group, multi-country,

multi-centre study on gastrointestinal tolerance.

**Intervention**

Administration of a tube feed different than the standard used tube feeds for a period of max 14 days.

**Study burden and risks**

Most assessments are standard practice at the ICU or done in routinely collected blood samples or urine samples. As such, no major issues are foreseen on the burden of the patient.

The test product is an adaptation of a commercially available peptide feed. No issues have been reported for this peptide feed for more than 15 years. The adaptation is done according to the most recent guidlines on feeding ICU patients (more protein and energy). Therefore, we don*t expect any issues regarding the use of this adapted peptide feed. The control product is a commercial available tube feed. Like in every clinical trial subjects will be closely monitored for (serious) adverse events.

If it appears that a patient needs a specific tube feed (e.g. diabetic tube feed), then the administration of the study product will be stopped and feeding with the required specific tube feed will be started. The physician will decide which specific tube feed should be used in the best interest of the patient.

The participants receiving the upgraded peptide feed might potentially benefit, because the upgraded peptide feed might be better tolerated. Improved GI tolerance might improve nutritional status and consequently minimize weight loss. This will favour recovery and improve quality of life post-discharge.

# 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

- Age ><=18 years;
- Admitted to the ICU;
- Expected to be on tube feeding for ><=5 days;
- Start of tube feeding within 48 hours after ICU admission

## Exclusion criteria

- Requiring other tube feed for medical reason;
- Not suitable for tube feeding;
- Allergy or intolerance for cow*s milk protein, soy or pea protein;
- Gastrointestinal disease such as Crohn*s or Ulcerative Colitis or other conditions affecting absorption such as short bowel syndrome;
- Pancreatic, liver or renal failure;
- Sequential organ failure assessment (SOFA) score >12 within first 24 hours after admission;
- Being pregnant;
- Participating in another clinical intervention trial

# Study design

## Design

| | |
|---|---|
| Study phase: | 2 |
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |
| Control: | Active |
| Primary purpose: | Treatment |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-01-2017 |
| Enrollment: | 10 |
| Type: | Anticipated |

# Ethics review

Approved WMO

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| Date: | 24-01-2017 |
| Application type: | First submission |
| Review commission: | IRB Nijmegen: Independent Review Board Nijmegen (Wijchen) |

# 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.

## In other registers

| Register | ID |
| --- | --- |
| CCMO | NL58904.072.16 |