# CONvalescence of FUnCtional outcomes after ICU Stay by oral protein supplementation
# The CONFUCIUS oral protein supplementation trial

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The primary objective is to investigate the effect of 6 weeks porcine protein supplementation versus an isocaloric carbohydrate (maltodextrin) on the composite endpoint of physical recovery.

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

## Summary

### ID

NL-OMON50646

**Source**
ToetsingOnline

**Brief title**
CONFUCIUS oral protein supplementation trial

### Condition

- Other condition

**Synonym**
intensive care, recovery post-ICU

**Health condition**

na IC opname

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Ziekenhuisvoorzieningen Gelderse Vallei
**Source(s) of monetary or material Support:** Rousselot,Stichting IC Research en Rousselot

## Intervention

**Keyword:** Post-ICU, Protein, Recovery, Supplement

## Outcome measures

### Primary outcome

A composite endpoint of hand grip strength, Hand-held Dynamometer m. quadriceps fem, Hand-held Dynamometer m. biceps brachii and 6 Minute walking test at t=2 (hospital discharge), t=3 (day 42 = end of intervention) and t=4 (3 months follow-up).

### Secondary outcome

- Handgrip strength assessed with Jamar dynamometer at T=3.

- Muscle strength leg assessed with HHD m. quadriceps fem. at T=3.

- Muscle strength arm assessed with HHD m. biceps brachii at T=3.

- Exercise capacity assessed with 6 Minute Walking Distance at T=3.

- Lower extremity muscle function assessed with TCST at T=3.

- CPAx at T=2.

- MRCsum at T=2, T=3 and T=4.

- Barthel score at T=3.

- Rockwood Clinical Frailty Scale at T=3.

- Body composition (BIA) at T=2, T=3 and T=4.

- Plasma AA concentrations at T=3.

- ICU readmission after ICU discharge

- Hospital readmission after hospital discharge

- Overall survival status

# Study description

### Background summary

Patients, discharged from the Intensive Care Unit, frequently suffer from muscle weakness. During ICU stay, people lost their muscle mass, caused by immobilization and inflammation during critical illness.
The two main factors involved in rehabilitation are exercise and optimal nutrition intake. Therefore, protein intake is essential for muscle recovery. Studies showed that protein requirements are often not met. Research has been done with increased protein intake during ICU stay and in other patient groups after hospital discharge. These studies showed mixed positive outcomes. However, a study on protein supplementation during the post-ICU period is limiting.

### Study objective

The primary objective is to investigate the effect of 6 weeks porcine protein supplementation versus an isocaloric carbohydrate (maltodextrin) on the composite endpoint of physical recovery.

### Study design

A randomiszed controlled double blinded trial.

### Intervention

One group receives daily 2 sachets of 22 g porcine protein, so in total 44 g per day.
The other group receives daily 2 sachets of 21 g maltodextrin, so in total 42 g per day.

### Study burden and risks

In total, 36 mL blood will be collected. For the first sample, blood can be

taken from the arterial line, so patients will hardly notice this. Besides, one tube of 3 mL will be taken. Later on in the study, blood samples will be taken from the patients, which can cause little discomfort.

Furthermore, patients will have 4 study days. On 2 days, they are asked to return to the hospital. On the other 2 days, patients are still in the hospital. During these appointments, patients have to perform several tests. They have to perform tests with i.e. the physiotherapist and blood samples will be collected. The last visit will be planned (if possible) at the same day as the 3-month follow-up, which is standard of care. In this case, measured will not be performed twice. And they are asked to fill in the questionnaires. At T=3 and T=4, patients can fill these in at home. The questionnaires could be confronting or exhausting.

Patients have to ingest the food supplement twice a day for a period of 6 weeks. And they have to keep a food diary on 8 days during the entire study period.

Maltodextrin is frequently used in studies, so the risk is very small. The risk for the protein group is also expected to be very small. High risk groups are excluded from the study,

## 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

1. Age >= 18 years
2. Living at home before hospital admission
3. Minimum ICU stay of 72 h
4. Informed consent

## Exclusion criteria

1. MRC sum score <= 24 or 48 >= at ICU discharge
2. Barthel Index <14 before ICU admission
3. Allergy/intolerance for study product
4. Serum creatinin > 173 mcmol/l (renal dysfunction)
5. Inclusion in other intervention trial since ICU admission
6. Inflammatory Bowel Disease
7. Zwangerschap
8. Underlying disease in which in the eyes of the attending physician, the protein or carbohydate supplement could form a risk for the patient

# Study design

## Design

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Completed |
| Start date (anticipated): | 20-04-2022 |
| Enrollment: | 72 |
| Type: | Actual |

## Ethics review

Approved WMO

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|---|---|
| Date: | 17-03-2022 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

## 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 | NL79158.091.21 |