# PGE2 levels, autophagy flux and mitochondrial function in ICU patients on enteral nutrition.

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Studies of ex vivo muscle cell autophagy flux, leucocyte mitochondrial function and oxylipins, specifically prostaglandin E2 (PGE2) in critically ill patients during admission to an intensive care unit (ICU).

Ethical review	Approved WMO
Status	Will not start
Health condition type	Metabolism disorders NEC
Study type	Observational invasive

# Summary

### ID

NL-OMON52319

**Source** ToetsingOnline

Brief title ProMICstudy

### Condition

• Metabolism disorders NEC

#### **Synonym** energy metabolism variance, Mitochondrial dysfunction

### **Research involving**

Human

## **Sponsors and support**

**Primary sponsor:** Ziekenhuisvoorzieningen Gelderse Vallei **Source(s) of monetary or material Support:** ICU Research foundation Gelderse Vallei Ziekenhuis Gelderse Vallei

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### Intervention

Keyword: Autofagy flux, Intensive Care, Mitochondrial dysfunction, Prostaglandin E2

### **Outcome measures**

#### **Primary outcome**

Autophagy flux measured in primary human myotubes incubated for 24 hours with serum from ICU patients, mitochondrial function in peripheral blood mononuclear cells (PBMCs) measured by functional respirometry (oroboros) and prostaglandin E2 (PGE2) levels as measured by LCMSMS.

#### Secondary outcome

- Investigate the localization of autophagy flux and of autophagy changes at different time points

- To determine if and how parameters of the hypermetabolic inflammatory state are related to the progression of mitochondrial function in IC patients

- To determine if and how progression of mitochondrial function is related to physical performance and clinical outcomes in IC patients

- To examine how mitochondrial dynamics change over time and how this is associated with mitochondrial function in IC patients

- Investigate the oxylipin profile measured by LCMSMS and lipopolysaccharide (LPS) levels

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- To examine how prostaglandin levels are related to inflammatory cytokine

levels.

- To determine how oxylipin levels are associated with changes in autophagy and

mitochondrial function and vise versa.

# **Study description**

#### **Background summary**

Hospital Gelderse Vallei's close ties with Wageningen University and the Karolinska Institute provide the opportunity to investigate the proposed association between protein supply and functional disease outcome at the basal level by measuring autophagy flux, mitochondrial function and prostaglandin levels. This study will examine the explanations behind the associations.

### **Study objective**

Studies of ex vivo muscle cell autophagy flux, leucocyte mitochondrial function and oxylipins, specifically prostaglandin E2 (PGE2) in critically ill patients during admission to an intensive care unit (ICU).

### Study design

This study consists of a combination of 3 single-centre observational cohort studies in patients participating in the PRECISe trial.

#### Study burden and risks

The included patients will already have an arterial catheter in situ; therefore, the blood draw in this case poses minimal risk and is completely painless. There are no direct benefits for the included patients. However, this study may provide important information that will add value to the results of the PRECISe trial. In this way, mechanisms that have not been studied before may be revealed and may contribute to a better understanding about autophagy flux, metabolism, and metabolism in IC patients.

# 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. Patient partipates in PRECISe trial
- 2. Adult >= 18 years-old admitted to the ICU
- 3. Unplanned ICU admission
- 4. Invasive mechanical ventilation initiated <24 hours of ICU admission
- 5. Expected ICU stay on ventilator support of >= 3 days

## **Exclusion criteria**

- 1. Contraindication for enteral nutrition
- 2. Moribund or expected withholding of treatment
- 3. Kidney failure with \*no dialysis\*-code on admission

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- 4. Hepatic encephalopathy
- 5. Body-mass index <18 kg/m<sup>2</sup>

# Study design

## Design

Study type: Observational invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Basic science	

### Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	60
Туре:	Anticipated

# **Ethics review**

Approved WMO	
Date:	01-04-2022
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

# **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

ССМО

**ID** NL78150.068.21