

# Nutrition and survival of critically ill patients

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 26/06/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/07/2023	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Nutrition is an essential part of daily life. Critically ill patients largely depend on artificial (non-natural) nutrition to prevent losing muscle and to support healing. The optimal type of artificial nutrition in these patients is, however, unknown, and there is a lot of scientific controversy on that issue. Nutritional therapy has been researchers using randomised studies with different patient groups getting different types of nutrition by chance. However, the results of these studies have been criticized because they may have been obtained in specific patient subgroups not representing the typical critically ill patients. Another way to analyse nutritional therapy is by conducting observational studies. In these studies, doctors provide that type of nutrition to a patient which they believe would help them the best; thereby, many different types of nutrition will be used. At the end a statistical analysis is necessary to find out which therapy is optimal (the best). A major advantage of observational studies is the fact that a large number of patients can be analysed thereby allowing a generalisation of the findings. A disadvantage is that the reliability of the results depends on the quality of the statistical analysis, which has to consider many other variables such as age or severity of the underlying disease to be sure that a better outcome is in fact related to a certain type of nutritional therapy. A further problem is the precise description of the type of nutrition, which may vary on a day to day basis, which may contain different amounts of calories or of protein, fat and carbohydrates, and which may be given through a natural way (by mouth) or artificially (by giving nutrients through a tube into the stomach, or through a catheter into a large vein). All these problems or variations could not be addressed by standard statistical analyses making the results of observational studies also uncertain. The aim of this study is to develop new statistical methods allowing a more reliable analysis of nutrition therapies as they are being documented in observational studies.

### Who can participate?

Patients aged 18 and older who have been treated in the ICU for 96 hours and treated with artificial nutrition.

### What does the study involve?

Participants have their data collected about their daily artificial nutrition after ICU admission and are followed up 60 days after to see if they were discharged or died while in hospital. Researchers review this data and evaluate hospital length and mortality to see how to analyse nutrition therapies.

What are the possible benefits and risks of participating?

There are no benefits or risks with participating.

Where is the study run from?

This study consists of registry data collected from Canadian hospitals and the data analysis takes place in Ludwig-Maximilian University Munich (Germany).

When is the study starting and how long is it expected to run for?

March 2012 to April 2017

Who is funding the study?

Ludwig-Maximilian University Munich (Germany)

Who is the main contact?

Professor Wolfgang Hartl

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## Contact information

### Type(s)

Scientific

### Contact name

Prof Wolfgang Hartl

### Contact details

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## Additional identifiers

### Protocol serial number

1

## Study information

### Scientific Title

Caloric intake and short-term survival of critically ill patients

### Study objectives

To examine the association between the magnitude of caloric supply and short-term survival of critically ill patients.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethical approval is not required as this study analyses the data from a large international registry ("nutrition practice in ICUs", [www.criticalcarenutrition.com/ins](http://www.criticalcarenutrition.com/ins)). Data is from 451 intensive care units and each has local institutional review boards approval.

**Study design**

Retrospective analysis of prospectively collected data incorporated in prevalence surveys of nutrition therapies (for details see [www.criticalcarenutrition.com/ins](http://www.criticalcarenutrition.com/ins))

**Primary study design**

Observational

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Critically ill patients

**Interventions**

To be incorporated into the registry, treating physicians had to collect information on daily artificial nutrition up to a maximum of 11 days after ICU admission. If the length of stay on the ICU had been shorter, the number of days for which nutrition had been documented, was correspondingly lower. Follow-up either lasted up to a maximum of 60 days after ICU admission (if the patient was still hospitalized), or up to the day when the patient either had died (while still being in the hospital), or had been discharged alive from the hospital.

Researchers reviewed the registry and collected data that contains information on hospital length of stay (if a patient had died or had been discharged before day 60 after admission), or on the fact that a patient had survived up to day 60 after admission while still being in the hospital. Due to or statistical concept, this information could not be used as it had been provided. For our statistical analysis a "pseudo"-30-day mortality is used either assuming that patients discharged alive before that day had actually survived up to that day (best case scenario), or that these patients had died after discharge (worst case scenario). Only patients who had died in hospital before day 30 or who had been alive at day 30 while still being hospitalized did not require such assumptions.

**Intervention Type**

Other

**Primary outcome(s)**

60 day hospital survival is measured using the data from the registry.

**Key secondary outcome(s)**

There are no secondary outcome measures.

**Completion date**

30/04/2017

# Eligibility

## Key inclusion criteria

1.  $\geq 18$  years of age
2. Must have been treated in an ICU for at least 96 hours
3. Must have received artificial (enteral or parenteral) nutrition on at least one day during the first 96 hours of their ICU stay

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

## Sex

All

## Total final enrolment

21000

## Key exclusion criteria

1. Survival time shorter than 4 days or patient discharged from ICU within 4 days
2. Nutrition protocol missing before the end of patient stay in ICU or the end of the protocol
3. Phase while still in ICU (whichever comes first;)
4. Neither enteral nor parenteral nutrition during the first 4 days of nutrition protocol
5. No mechanical ventilation during the first 4 days of nutrition protocol
6. Exclusive oral intake after extubation
7. Patients with missing data

## Date of first enrolment

15/03/2014

## Date of final enrolment

01/10/2014

# Locations

## Countries of recruitment

Canada

Germany

**Study participating centre**  
**Ludwig-Maximilian University**  
Department of General  
Visceral, Transplantation, and Vascular Surgery  
University School of Medicine  
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**Study participating centre**  
**Statistical Consulting Unit**  
Department of Statistics  
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## **Sponsor information**

**Organisation**  
LMU Munich (Ludwig-Maximilians-Universität München)

**ROR**  
<https://ror.org/05591te55>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
Ludwig-Maximilians-Universität München

**Alternative Name(s)**  
Ludwig Maximilians University Munich, LMU Munich, LMU

**Funding Body Type**  
Government organisation

**Funding Body Subtype**  
Local government

**Location**  
Germany

## Results and Publications

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be stored in a publically available repository. All raw data contained in the registry are available through the international “nutrition practice in ICUs” registry. Principles of the statistical analytical plan are available at <http://biostatistics.oxfordjournals.org>

**IPD sharing plan summary**  
Stored in repository

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/04/2019		Yes	No
<a href="#">Results article</a>	protein intake and clinical outcome	11/01/2022	11/07/2023	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes