ISRCTN17829198 https://doi.org/10.1186/ISRCTN17829198

Nutrition and survival of critically ill patients

Submission date
20/06/2017

Recruitment status
No longer recruiting

Registration date
26/06/2017

Overall study status
Completed

Last Edited
11/07/2023

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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). Data is from 451 intensive care units and each has local 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)

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
There are no secondary outcome measures.

Overall study start date
30/03/2012

Completion date
30/04/2017

Eligibility

Key inclusion criteria
1. ≥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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
> 9000

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
Grosshadern Campus
Marchioninistr. 15
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Study participating centre
Statistical Consulting Unit
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Sponsor information

Organisation
LMU Munich (Ludwig-Maximilians-Universität München)

Sponsor details

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Sponsor type
University/education

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

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

Intention to publish date
31/12/2017

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?
Results article	results	01/04/2019		Yes	No
Results article	protein intake and clinical outcome	11/01/2022	11/07/2023	Yes	No