Micronutrient levels and nutritional status in critical illness

Published: 07-03-2023
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Assess nutrition-related biomarkers in plasma and urine samples at ICU admission

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON53793

Source
ToetsingOnline

Brief title
NUTRI-ICU

Condition

- Other condition

Synonym
Post-intensive care syndrome, recovery after critical illness

Health condition

Herstel na kritische ziekte

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden
Source(s) of monetary or material Support: Provincie Fryslân

Intervention

Keyword: Intensive care, Micronutrients, Nutrition

Outcome measures

Primary outcome

Biomarker status in blood and urine between baseline

Markers general health: hemoglobin (Hb), mean corpuscular volume

(MCV), glucose, c-reactive protein (CRP), thyroid stimulating hormone

(TSH), creatinine + glomerular filtration rate (eGFR), alanine

aminotransferase (ALAT), urea, albumin, total protein, lipid profile

Micronutrients: potassium, calcium, sodium, vit B11, vit B1, vit

B6, vit B12, vit D, Vit C, ferritin, magnesium, chloride, phosphorus

Secondary outcome

- Total number of micronutrient deficiencies at baseline

- Dietary intake at baseline

Measured with: dietary intake diary

- Objective nutritional status and muscle thickness at baseline

Measured with: bioimpedance analysis, ultrasound assessment of

quadriceps muscle layer thickness QMLT

Study description

Background summary

A significant proportion of patients admitted to the Intensive Care Unit (ICU) is unable to fully recover, even when the initial cause of their illness has been treated. Inadequate dietary intake prior to admission and during the recovery phase may leave patients in a frail physical state, limiting

rehabilitation potential. Commonly used methods to assess nutritional intake and nutritional status are highly impacted by various disease-related confounders and reporting bias. We hypothesise that a combined assessment of biomarkers in plasma and urine may provide a more accurate overview of nutritional status before and after ICU-admission.

Study objective

Assess nutrition-related biomarkers in plasma and urine samples at ICU admission

Study design

Cross-sectional study

Study burden and risks

In addition to standard care ICU treatment, blood and urine samples will be collected in the first 24 hours of ICU-admission in all patients. In addition, ultrasound measurement of the upper leg will be conducted within 72 hours of admission. When feasible, patients will be asked to complete a dietary intake diary during admission.

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

Admission to the Intensive Care Unit
Able to read and understand Dutch

Exclusion criteria

Comorbidity highly affecting gut absorption (e.g. post-bariatric surgery)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	08-05-2023
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	07-03-2023
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	02-08-2023
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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	NL83298.099.22
Other	Onderzoek wordt geregistreerd na toestemming RTPO