Malnutrition in Polytrauma Patients

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

Summary

ID

NL-OMON52804

Source
ToetsingOnline

Brief title
MaPP

Condition

- Other condition

Synonym
poor nutrition, undernutrition

Health condition

Ernstig ongevalsletsel (polytrauma)

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: onderzoeksfonds van de afdeling Traumachirurgie LUMC

Intervention

Keyword: Malnutrition, Polytrauma

Outcome measures

Primary outcome

The primary outcome in this study is the complication rate.

Secondary outcome

Other study parameters include pre-existent and in-hospital malnutrition,

hospital length of stay (HOS-LOS), intensive care length of stay (ICU-LOS),

ventilator-free days, surgery, discharge disposition, readmission,

calorie/protein deficit and biomarkers, and functional outcomes (Glasgow

Outcome Scale Extended and EQ-5D).

Study description

Background summary

Severely injured patients (polytrauma patients) are at risk of considerable harm from malnutrition due to disease-related malnutrition with inflammation. Recognition of sub-optimally nourished polytrauma patients and assessment of their nutritional needs is crucial in order to improve their clinical outcomes. Even though this is acknowledged, there is little knowledge of (the risk of) malnutrition and its consequences in the polytrauma patient population. Therefore the goal of our study is to investigate the prevalence of both pre-existent and in-hospital developed malnutrition in polytrauma patients admitted to the intensive care unit (ICU), to assess the association between malnutrition and complications, to determine the association between biomarkers (pre-albumin, albumin, C-reactive protein [CRP]) and malnutrition and lastly, to assess the relationship between malnutrition and long term outcomes.

Study objective

The primary objective is to investigate whether polytrauma patients (Injury Severity Score [ISS] >= 16) admitted to the ICU who have or develop malnutrition have a higher complication rate than patients who are and remain

well-nourished. Secondary aims are to determine the prevalence of pre-existent malnutrition, the incidence of in-hospital developed malnutrition and the predictive value of (bio)markers for malnutrition.

Study design

This observational prospective cohort study will be performed at three Level-1 trauma centers in the United States and two Level-1 centers in the Netherlands. The three centers in the United States are Massachusetts General Hospital (MGH) and Brigham and Women*s Hospital in Boston, and Ryder Trauma Center in Miami. The two participating Dutch centers are locations of the Trauma Center West Netherlands, and include Leiden University Medical Center (LUMC) in Leiden and Haaglanden Medical Center Westeinde in The Hague.

Study burden and risks

This observational study poses no additional burden, risk and benefits for the study participants.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
• >=18 years of age
• Polytrauma patient (Injury Severity Score >=16)
• Blunt trauma mechanism
• Admitted to the ICU

Exclusion criteria

• <48hr admission to the intensive care unit
• Transfer from other hospital to participating center
• Patients with burn wounds
• Penetrating trauma mechanism

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	16-08-2018
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO Date:	21-02-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	02-05-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	31-07-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	25-02-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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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	NL64016.058.17

Study results

Date completed: 01-04-2023

Results posted: 01-05-2024

Summary results
Trial ended prematurely

First publication
01-05-2024