Malnutrition and outcome in hospitalized children in Europe (ESPEN Network Grand Project)

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

Summary

ID

NL-OMON34719

Source
ToetsingOnline

Brief title
Malnutrition in hospitalized children

Condition

- Other condition

Synonym
disease related malnutrition, malnutrition

Health condition

ondervoeding/slechte voedingstoestand

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: ESPEN Network Grant

Intervention

Keyword: malnutrition, nutritional status, outcome, screening

Outcome measures

Primary outcome

The primary outcome of the trial will be the length of hospital stay (days).

Secondary outcome

The secondary outcomes are:

• change of anthropometry during stay (e.g. percent weight loss per hospital

day, based on difference between admission weight and discharge weight)

• frequency of infectious complications (number of days with temperature

>38,5°C, number of days with days with antibiotic use)

• frequency of gastrointestinal complications (number of days with vomiting,

number of days with diarrhoea)

• muscle strength (kids >= 6 years)

• number of days with need for nutritional support during stay in any form, in

addition to any prior to admission

Study description

Background summary

Disease-related malnutrition affects 20-50 % of adult hospitalized patients and was shown to seriously affect relevant outcomes, such as recovery from disease or surgery, length of hospital stay and cost of care (Norman et al 2008).

In paediatric patients, disease associated malnutrition has even more severe consequences on a short- and long-term basis, for example with respect to disease course and mortality, complication rates, growth, development, well-being and long-term health outcomes (Goulet and Koletzko 2004; Koletzko et al 2008). According to prior studies, malnutrition affects about 15-30 % of hospitalized children in Europe (ESPGHAN 2005, Pawellek et al 2008, Joosten and Hulst 2008). However, available criteria for defining malnutrition in paediatric patients are inconsistent, not based on firm evidence, and not generally agreed upon. Current guidelines do not address assessment of and screening for childhood malnutrition. Therefore, a large number of affected children are not adequately diagnosed.
One aim of this study is to assess the prevalence of malnutrition and patients at risk for malnutrition among hospitalized children across Europe. In addition criteria to link anthropometric measurements and the prediction of outcome, i.e. length of hospital stay, shall be established. A further goal then is to establish agreed, evidence-based criteria for malnutrition in children with the purpose of leading to an agreed, evidence-based screening tool for paediatric malnutrition in developed countries. This tool shall include a set of simple questions, based on previously suggested tools. Thereby this study will provide a strong basis for implementing evidence-based nutritional interventions in paediatric patients by harmonisation of diagnostic criteria for childhood malnutrition in developed countries.

These two hypotheses will be tested:
• Global nutritional status of hospitalized children in Europe can be assessed in a meaningful way by standardized anthropometric measures and simple questions related to patient*s history, based on previously suggested paediatric screening
• Nutritional status of hospitalized children at admission in Europe is associated with a relevant clinical outcome.

Study objective

The purpose of this study is to characterize in hospitalized children across Europe:
• the prevalence of malnutrition on admission and at discharge,
• the effects of malnutrition on outcomes, such as length of hospital stay and occurrence of infectious complications,
• the predictive values of different descriptors of malnutrition for relevant outcomes,
• the prevalence of paediatric hospital patients at risk for malnutrition, as well as predictors of increased risk,
• the relative value of proposed paediatric screening tools, for identifying a subpopulation with increased risk for malnutrition, for relevant outcomes

Study design

This is a prospective European multi-centre cohort study.
The following data will be collected by the named assessors using specifically designed case report forms. Data will be obtained at admission and at discharge of all patients which have been rated eligible by the assessor. All collected data will be treated, analysed and archived confidentially.

1. Interview at admission
A. Demographic and medical data: gender, date of birth, date of admission, ethnic back ground, chronic disease, ICD 10 classification for main diagnosis, ICD 10 classification for reason of admission, quality of life assessment

B. Questionnaire data for nutritional status: high risk disease, acute admission/condition effect on nutrition, subjective clinical assessment, dietary intake and nutritional losses, frequency and duration of gastrointestinal symptoms, weight loss or poor weight gain, previous dietary support.
This questionnaire integrates the questionnaires of three previous nutrition screening tools, sorted by items: The Paediatric Yorkhill Malnutrition Score (PYMS), the nutritional risk screening tool, called STRONGKids (Hulst et al 2009) and the screening tool for the Assessment of Malnutrition in Paediatrics (STAMP) (McCarthy et al 2008).

2. Anthropometric and BIA measures at admission: weight (kg), height (cm), mid-upper arm circumference (cm) , Triceps skin fold thickness (mm), Handgrip strength (kg), Bioelectrical impedance analysis (BIA), in those centres where feasible, due to available BIA equipment
The admission data has to be collected within 24 hours after admission time. BIA measurement will be performed with all children aged three years or older. Handgrip strength will be performed with all children aged six years or older. Hydration status, handedness and time of last eating/drinking are to be recorded.

3. Anthropometric and BIA measures at discharge: weight (kg), mid-upper arm circumference (cm) , Triceps skin folder thickness (mm), Handgrip strength (kg), Bioelectrical impedance analysis (BIA), in those centres where feasible Anthropometry is going to be repeated at discharge for all patients with LOS >= 96 hours, when possible. Otherwise the last measured weight is to be recorded.

4. Collection on outcome data: date of discharge (days of hospital stay), number of days with temperature >38.5oC, number of days with diarrhoea, number of days with vomiting, number of days with antibiotic use, number of days with need for nutritional support during stay in any form, in addition to any prior to admission, further complications (Infections, other)

Data will be derived from the hospital record.

Study burden and risks

The study takes place while the child is hospitalized. Data are collected at two time points: admission and discharge. There is no need for additional hospital visits, blood drawings or invasive measurements. The study comprises of:
- Short interview with questions related to previous health, weight loss, gastrointestinal symptoms and nutritional intake.
- Measurements of weight and length (standard care)
- Measurements of mid-upper arm circumference and triceps skin fold thickness
- Measurements of bioelectrical impedance analysis (BIA) (children >= 3 years)
- Measurement of handgrip strength (children >= 6 years)

The burden for the child is minimal, because some of the measurements and questions are part of the standard hospital care and admission procedure. The additional measurements are the measurements of mid-upper arm circumference, triceps skin fold thickness, BIA and measurement of handgrip strength. The skinfold measurement can be experienced as unpleasant. However, this measurement takes only a few seconds and can be compared in terms of burden with the measurement of blood pressure. The BIA measurement has no burden: two electrodes are placed at a hand and a foot of a child, which are comparable tot electrodes placed when taking an ECG. The child does not notice anything from the measurement itself. In order to measure the hand grip strength the child must squeeze in a tool, this has no burden.

The research question can only be answered by including children as subjects, because the aims of the study are specifically focused on children. Measurement of nutritional status and screening tools for malnutrition that have been developed for adults, can not be applied to children because age specific characteristics such as growth, have to be taken into account.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

•Children admitted to the participating hospitals during the study period
•Age between 1 month and 18 years
•Expected hospital stay exceeding 24 hours
•Parents/caregivers, as well as those patients capable to comprehend, agree to participation and sign the informed consent form

Exclusion criteria

•Infants with premature birth (<37 weeks gestational age) during the first 12 months of life
•Infants < 1 month of age
•Patients >= 18 years of age
•Children in need of intensive care
•Children admitted to day-care (LOS < 24hours)
•Patients admitted for elective reasons with an expected hospital stay <24 hours

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-06-2010
Enrollment:	220
Type:	Actual

Ethics review

Approved WMO

Date:	03-06-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL31893.078.10