

Understanding of malnutrition in people with complex multiple disabilities.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Chromosomal abnormalities, gene alterations and gene variants
Study type	Observational invasive

Summary

ID

NL-OMON36282

Source

ToetsingOnline

Brief title

Malnutrition in people with complex multiple disabilities.

Condition

- Chromosomal abnormalities, gene alterations and gene variants
- Mental impairment disorders

Synonym

complex multiple disabilities

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Complex multiple disabilities, Malnutrition

Outcome measures

Primary outcome

Concerning measurement of body composition, the Deuterium dilution method will be used. A blood sample will be collected for measurement of nutrients.

Furthermore, clinical parameters (weight, height and abdominal girth) will be measured.

Secondary outcome

A questionnaire will be submitted to the carer responsible for the patient.

This questionnaire contains questions about the health status and the use of medication by the patient, the intake of specific food and nutrients, feeding habits, behavioural problems and problems that occur during feeding as well as the (probable) appreciation of feeding by the patient.

Study description

Background summary

Underweight is more prevalent in people with a mental handicap than in people without a mental handicap, especially in people with a severe mental handicap. It is unknown if these people are malnourished. There is no validated screening instrument available to determine the nutrition status in people with complex multiple disabilities. Research regarding malnutrition based on body composition and nutrients instead of anthropometric data is important.

Study objective

The aim of the study is to understand the nutritional status of people with complex multiple disabilities through measurement of body composition and nutrients.

The primary objective of the study is:

What percentage of people with complex multiple disabilities are malnourished, based on altered body composition and nutrients?

Understanding the nutritional status of these patients is important in order for them to receive appropriate and effective treatment. This treatment is of interest for general health and the quality of daily life.

Study design

Observational study.

Study burden and risks

The risks include taking a blood sample once. Since this will, if possible, be requested in addition to a regular blood withdrawal and collection of urine samples will be done using wads of cotton wool, the risks are negligible and the burden of participation to the study is minimal. If no regular blood withdrawal is scheduled, a blood withdrawal will be planned for the study. The questionnaire will be submitted to the carer responsible for the patient. In case the carer does not know the answer to a question, the physician of the institution or the dietician will be consulted. The questionnaire therefore is not a burden for the patient.

Contacts

Public

Medisch Universitair Ziekenhuis Maastricht

Postbus 5800
6202 AZ Maastricht
NL

Scientific

Medisch Universitair Ziekenhuis Maastricht

Postbus 5800
6202 AZ Maastricht
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Person with complex multiple disabilities;
- Living in a care institution participating in the Governor Kremers Centre (GKC);
- Chronically confined to a wheelchair or bedridden;
- 18+ years.

Exclusion criteria

- Parenteral nutrition;
- Serious infection;
- Terminal illness.

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 01-02-2011

Enrollment: 125

Type:

Actual

Ethics review

Approved WMO

Date: 18-10-2010

Application type: First submission

Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date: 12-01-2011

Application type: Amendment

Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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

CCMO

ID

NL32655.068.10