Impact Protein intake on growth in Cystic Fibrosis

Published: 24-11-2009
Last updated: 04-05-2024

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Ethical review	Approved WMO
Status	Pending
Health condition type	Exocrine pancreas conditions
Study type	Interventional

Summary

ID

NL-OMON33049

Source
ToetsingOnline

Brief title
Impact Protein intake on height growth in Cystic Fibrosis

Condition

- Exocrine pancreas conditions

Synonym
Cystic Fibrosis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: children, cystic fibrosis, height growth, protein

Outcome measures

Primary outcome

The main study parameters are the differences in heigth and lean body mass.

Based on these parameters, the growth will be determined. The side effect

parameters are the differences in weight and urea.

Secondary outcome

The side effect parameters are the differences in weight and urea.

Study description

Background summary

Children with cystic fibrosis (CF) have less net protein anabolism than children without CF, and the result is retarded growth in the CF patients. Numerous factors are likely to contribute to growth impairment and delayed puberty in children with CF. The major factors that adversely affect growth are malnutrition (from malabsorption, inadequate intake and increased requirements), chronic inflammation, diabetes mellitus, liver disease, lung disease and corticosteroid treatment. The protein intake above that recommended by the CF Foundation would further stimulate whole-body protein synthesis.

Study objective

The primary objective of this study is to establish the clinically relevance of extra protein supplementation on the height growth at children with Cystic Fibrosis. The secondary objectives of this study are to measure the effects of protein supplementation on the lean body mass by CF children with a retarded growth.

Study design

The study is a cross-over randomized controlled trial, which each patient served as his or her own control subject for protein supplementation.

Intervention

Each patient will receive in random order above the normal recommended feeding intake 2 g protein extra * kg*1 * d*1 in the form of protein powder. The energy, fat and carbohydrate intakes stay the same. Each patient crossing over in effect serves as their own control. The data are analyzed according to the original intention to treat.

Study burden and risks

Subjects are expected for 3 à 4 months for a control, additional to this control for this study the body composition will be measured with the BIA and the growth will be determined with different parameters. Before this control is kept up a 3dd food record. (Appendix I)
The protein supplement is a commercially available safe protein powder. No risks are involved.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

* Boys and girls with the age 4*12 y
* Prepubertal status
* Mild lung disease (FEV1 >75%)
* Informed consent signed by parents

Exclusion criteria

* Possible use of Corticosteroid

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2009
Enrollment:	15
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission

Review commission: METC Amsterdam UMC

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	NL28495.018.09