Longitudinal study of nutritional problems in children treated for cancer

Published: 10-08-2007
Last updated: 08-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Diabetic complications
Study type	Observational non invasive

Summary

ID

NL-OMON31072

Source
ToetsingOnline

Brief title
Nutritional problems in children with cancer

Condition

- Diabetic complications
- Miscellaneous and site unspecified neoplasms benign

Synonym
malnutrition

Research involving
Human

Sponsors and support

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

Intervention

Keyword: distress, HRQL, mealtime interaction, nutritional state

Outcome measures

Primary outcome

Nutritional intake (based on 3x 24 h diaries) and nutritional state (weight,

height, mid upper arm circumference (MUAC), skin thickness, Bio-impedance).

Secondary outcome

Health Related Quality of Life of the child, mealtime interaction and distress

of the parents.

Study description

Background summary

Each year in the Netherlands 500 children younger than 18 years develop cancer. Fortunately the surviving rates have dramatically improved in the recent decennia. Due to intensive treatment 70% of the children survive. As survival rates have improved, there has been an increased focus on supportive care. Nutrition is a supportive-care modality that has been associated with improved tolerance to chemotherapy and improved survival. Although the importance of a good nutritional state is widely accepted, figures of the nutritional state of children during treatment are not known. Dutch prevalence rates of under -or over nutrition of children treated for cancer are not available.
Neither is known how the children perform on nutritional intake, although it is clear that for many children eating sufficient is a great burden. Both physical and psychological determinants affect the nutritional intake. Children experience lot symptoms due to chemotherapy such as: nausea, anorexia, altered taste. Besides this the doctors, nurses and parents force children to eat enough. The child can use food refusal as a way to gain control in his/her life. Not wanting or not being able to eat is for the parents who suffer a lot emotional stress caused by the child*s illness, yet another burden. Therefore, the nutritional problems can have considerable impact on both the child and his/her parents.

Study objective

This study will focus on the nutritional problems described above of children treated for cancer. The study will describe: the nutritional state during treatment, the determinants affecting the nutritional intake and the impact of nutritional problems on child and parents.

Study design

Data will be assessed longitudinally at diagnosis, after 3 months, 6 months and 12 months measuring the nutritional state and with questionnaires for child and parent.

Study burden and risks

The first 6 months of this research are the most intensive. At three moments after diagnosis children and parents have to fill in questionnaires. At T1 short after diagnosis the questionnaire for parents consists of 234 items, at T2 3 months after diagnosis the questionnaire consists of 325 items and at T3 6 months after diagnosis the questionnaire consists of 194 items. The total time for answering the questionnaires varies from 45 min- 90 min. Children aged 5-8 years will answer questions about symptoms, HRQL and distress eating/tube feeding by structured interview (time about 30 min). Children aged 8-10 years will answer questions about symptoms, HRQL and distress eating/tube feeding either by structured interview or by self-administered questionnaires (time about 30-40 min). The method of data collection depends on the abilities of the child. For the children aged 11 and older questionnaires will be used to assess symptoms, HRQL, goals and distress (time about 50 min).
One year after diagnoses, at T4, nutritional state, mealtime interaction and HRQL will be assessed. This will be during a regular visit and will take about 15 minutes time.

No serious adverse events should be expected.

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 with cancer:
0-18 years
newly diagnosed cancer
thorough command of Dutch language
Healthy controls:
0-18 years
thorough command of Dutch language

Exclusion criteria

Both groups:
mental disability
Children with cancer:
relapse of cancer

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2007
Enrollment:	91
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL17977.042.07