Changes in body composition, dietary intake, and physical activity in children with cancer - a master protocol

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The overarching objective of this master protocol is to study the risk factors (personal, clinical and lifestyle factors) for-, and consequences of- , changes of nutritional status (both over- and undernutrition) in children with cancer. Based on...

Ethical review	Approved WMO
Status	Recruitment started
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON56855

Source
ToetsingOnline

Brief title
FITco study

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified
- Appetite and general nutritional disorders

Synonym
body composition, nutritional status, physical activity, exercise

Research involving
Human

Sponsors and support

Primary sponsor: Prinses Máxima Centrum voor Kinderoncologie

Source(s) of monetary or material Support: Collectebussenfonds

Intervention

- No intervention

Keyword: Body composition, Dietary intake, Pediatric oncology, Physical activity

Explanation

N.a.

Outcome measures

Primary outcome

For the initial cohort: changes of body size (BMI, MUAC), body composition (FM and FFM), dietary intake, and physical activity during and after treatment.

Sub-study A: the relationship between changes in FM in the first three months after diagnosis and the presence of bacteraemia during the first year of treatment.

Sub-study B: faecal microbiome (absolute numbers and diversity) in children with ALL, bone sarcoma, Hodgkin Lymphoma and healthy controls (siblings)

Sub-study C: functional capacity as defined by age specific scales.

Secondary outcome

For the initial cohort, there are no secundary study parameters/outcomes of the study.

Sub-study A:
- The relationship between nutritional status at diagnosis (underweight, normal weight, overweight, obesity), but also changes in FFM, BMI, and MUAC in the first three months after diagnosis and the presence of bacteraemie during treatment
- The relationship between nutritional status at diagnosis (underweight, normal weight, overweight, obesity), but also changes in FM, FFM, BMI, and MUAC in the first three months after diagnosis and toxicity during treatment
- The relationship between nutritional status at diagnosis (underweight, normal weight, overweight, obesity), but also changes in FM, FFM, BMI, and MUAC and survival outcomes (EFS and OS)
- The relationship between nutritional status at diagnosis (underweight, normal weight, overweight, obesity), but also changes in FM, FFM, BMI, and MUAC and health-related quality of life -Changes in FM, FFM, BMI, and MUAC over time, and risk factors associated (such as age, type of malignancy, treatment regime, dietary intake, and physical activity)
For sub-study B and C, there are no secundary study parameters/outcomes of the study.

Study description

Background summary

Poor nutritional status (which includes both undernutrition and overnutrition) in children being treated for cancer can result in decreased survival, increased treatment-related toxicity, and poor quality of life. However,
current evidence is based on studies of low quality, a limited number of patients, often cross sectional, focus on a specific patient group (mostly patients with hematological malignancies), or anthropometric data only (body
weight or body mass index). Besides weight and height, especially body composition (fat mass (FM) and fat free mass (FFM)) is widely believed to influence clinical outcomes. For example, excess FM may result in inadequate
dosing and diminished efficacy of chemotherapy on short-term, but may also exacerbate effects associated with obesity, like cardiovascular and metabolic
diseases on long-term.

Till now, the main focus has been on undernutrition in children with cancer. Emerging evidence shows that many children are also vulnerable to overnutrition and weight gain (particularly gain of FM) during treatment, for example as side effect from steroids often used in acute lymphoblastic leukaemia, which often extends into survivorship.

However, there are a lot of remaining questions:
1. Which anthropometric or body composition variables are most strongly associated with clinical outcomes: weight and height, or rather FM and FFM?
2. Which personal, clinical, and lifestyle factors are important risk factors for either over- or undernutrition throughout the course of cancer treatment?
3. Is over- or undernutrition related to toxicity, survival and quality of life in a heterogeneous group of children with cancer, or only in specific sub-groups who might benefit from additional supportive care?
4. What are effective strategies to improve nutritional status, and how does it influence clinical outcomes including toxicity, survival, and quality of life?

Study objective

The overarching objective of this master protocol is to study the risk factors (personal, clinical and lifestyle factors) for-, and consequences of- , changes of nutritional status (both over- and undernutrition) in children with cancer. Based on the results of this first phase, we will develop and evaluate interventions aiming to improve the nutritional status, to finally improve clinical outcomes (i.e., survival, toxicity, and quality of life) for children with cancer.

Study design

This is a master protocol for a longitudinal cohort study focusing on all relevant aspects of malnutrition, including body composition, dietary intake, and physical activity in children with cancer. The term master protocol refers to a study design that uses one overarching protocol to guide multiple, simultaneously occurring sub-studies to evaluate multiple diseases, therapies, clinical outcomes, or a combination of those within the same overall study

structure.

During this longitudinal cohort study, measurements will be performed and data will be collected at diagnosis, and 3, 6, 12, and 24 months after diagnosis.

Intervention

not applicable

Study burden and risks

This study will yield valuable information to enable personalized support regarding body composition, nutrition, and physical activity for future children with cancer. Risks and burden of participation within the initial cohort can be considered as minimal. Measurements of body composition using the Bodpod can be performed in approximately 5 minutes. The regular evaluations related to dietary intake (MijnEetmeter application) will take approximately 10 minutes per day for 3 days and the more extensive food frequency questionnaires (20 minutes) will only be applied at three timepoints (at start of the study, 12 months, and 24 months after diagnosis). The diary which needs to be kept during the Actigraph is worn takes 2 minutes per day for 7 days. Moreover, measurements are not painful (the blood withdrawal for research purposes will be combined with a regular blood draw as part of clinical care) and are always performed during planned visits to the hospital.

The data obtained in this study will be used to define high risks groups which might benefit from nutritional or physical interventions and to develop intervention studies aiming to prevent over- and undernutrition and possible detrimental changes in body composition during cancer treatment, ultimately leading to less treatment-related toxicity, better survival, and improved quality of life, both on the short- and long-term. In this way, future patients (and their parents) will benefit from the knowledge obtained in this study.

Contacts

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Trial sites

Trial sites in the Netherlands

Prinses Maxima Centrum voor Kinderoncologie
Target size: 500

Listed location countries

Netherlands

Eligibility criteria

Age
Newborns
Children (2-11 years)
Babies and toddlers (28 days-23 months)
Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion criteria

- Between 0 and 18 years
- Newly diagnosed with a haematological, solid, brain malignancy, or a craniopharyngioma
- Being able to read and / or understand Dutch (either on of the parents or children)
- Provided written informed consent

For sub-study A and C there are no additional inclusion criteria.

For sub-study B, only patients diagnosed with ALL, bone sarcoma, or Hodgkin Lymphoma – or a healthy sibling of children diagnosed with ALL, bone sarcoma, or Hodgkin Lymphoma will be included.

Exclusion criteria

- None

Study design

Design

Study phase:	N/A
Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Other type of control
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment started
Start date (anticipated):	19-12-2024
Enrollment:	500
Duration:	24 months (per patient)
Type:	Actual

Medical products/devices used

Product type:	N.a.
Registration:	No

IPD sharing statement

Plan to share IPD: Yes

Plan description
Nog nader te bepalen

Ethics review

Approved WMO

Date:	28-06-2024
Application type:	First submission

Review commission:	METC NedMec
Approved WMO Date:	18-03-2025
Application type:	Amendment
Review commission:	METC NedMec

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	NL86599.041.24
Research portal	NL-005598