Resting energy expenditure in children with cancer

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The primary objective is to investigate the resting energy expenditure of children with a hematological, solid or brain malignancy at diagnosis and during treatment. The secondary objective is to explore the body composition, physical activity and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Appetite and general nutritional disorders
Study type	Observational invasive

Summary

ID

NL-OMON54556

Source
ToetsingOnline

Brief title
ENERGICE study

Condition

- Appetite and general nutritional disorders

Synonym
Under- and overnutrition

Research involving
Human

Sponsors and support

Primary sponsor: Prinses Máxima Centrum voor Kinderoncologie
Source(s) of monetary or material Support: Kika

Intervention

Keyword: cancer, children, resting energy expenditure

Outcome measures

Primary outcome

Resting energy expenditure will be assessed using indirect calorimetry. Oxygen consumption and carbon dioxide production will be measured. The respiratory quotient will be derived from oxygen consumption and carbon dioxide production.

Secondary outcome

Body composition (fat and fat free mass) will be determined by bioelectrical impedance analyses. Physical activity will be assessed using an Actigraph. The intensity of physical activity (sedentary, light, moderate, and vigorous physical activity), steps per day and metabolic equivalents of physical activity will be derived.

Study description

Background summary

A balance between energy intake and energy requirement is crucial to maintain a healthy body weight. Components of total energy expenditure include resting energy expenditure, physical activity and diet induced thermogenesis, representing respectively 50-70%, 15-40% and 10% of total energy expenditure in children and adolescents. Since cancer and its treatment can influence all of these components, estimation of energy requirement in patients with cancer is challenging. Longitudinal data regarding resting energy expenditure in children with cancer throughout treatment are limited and showed contradictory results.

Study objective

The primary objective is to investigate the resting energy expenditure of children with a hematological, solid or brain malignancy at diagnosis and during treatment. The secondary objective is to explore the body composition,

physical activity and dietary intake of these patients. Furthermore, blood samples will be taken for cytokine analysis and validation of differences in metabolism on cellular-level. The present study will also be used to explore the feasibility of resting energy expenditure measurement before the start of treatment in children with cancer. Moreover, the validity of body composition measurement using the Tanita Body Composition Analyzer will be compared to the Bodystat QuadScan 4000.

Study design

The present study will have a prospective observational design. Measurements of resting energy expenditure, body composition, physical activity, and dietary intake will be performed at diagnosis and two times during treatment. Patients start participation in this study shortly after the start of treatment.

Study burden and risks

This study will yield valuable information to enable personalized support regarding nutrition and physical activity in children with cancer. Performing the measurements of resting energy expenditure, body composition, physical activity and dietary intake is considered a minimal burden for children with cancer. These data will be used to develop intervention studies aiming to prevent under- and overfeeding and possible detrimental changes in body composition during cancer treatment.

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

-Diagnosed with cancer
-Treated with chemotherapy
-Between 4-18 years old at the start of treatment
-Ability to comprehend Dutch (both reading and writing)

Exclusion criteria

-Prior diagnosis of cancer
-Having oxygen delivery
-Inability to lay still for 20 minutes
-Inability of completing an overnight fast prior to the measurement
-Having an electric implant, such as a pacemaker
-Having a biosensor, such as a glucose meter

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-12-2020
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO Date:	17-07-2019
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	10-09-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	15-10-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	23-05-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
Other	Netherlands Trial Register, NL7657
CCMO	NL69551.041.19