Resting energy expenditure in children with cancer

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neoplasm related morbidities
Study type	Observational non invasive

Summary

ID

NL-OMON20917

Source
NTR

Brief title
ENERGICE

Condition

- Neoplasm related morbidities

Health condition

Cancer

Research involving
Human

Sponsors and support

Primary sponsor:	Prinses Máxima Centrum Utrecht
Secondary sponsors:	Regiodeal Foodvalley

Source(s) of monetary or material Support:	NA

Intervention

Outcome measures

Primary outcome

REE will be assessed using indirect calorimetry. Oxygen consumption (VO_2) and carbon dioxide production (VCO_2) will be measured. The respiratory quotient (RQ) will be derived from VO_2 and VCO_2.

Secondary outcome

Body composition will be determined by bioelectrical impedance analyses (BIA). Fat mass (FM) and fat free mass (FFM) will be derived. Subsequently, the percentage of FM (%FM) and FFM (%FFM) will be calculated. 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 (METs) of physical activity will be derived. Dietary intake will be explored using three-day food records. A blood sample will be taken for cytokine analysis.

Study description

Background summary

Rationale: A balance between energy intake and energy requirement is crucial to maintain a healthy body weight. Components of total energy expenditure (TEE) include resting energy expenditure (REE), physical activity and diet induced thermogenesis, representing respectively 50-70%, 15-40% and 10% of TEE 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 REE in children with cancer throughout treatment are limited and showed contradictory results.

Study objective

REE will be assessed using indirect calorimetry. Oxygen consumption (VO_2) and carbon

dioxide production (VCO_2) will be measured. The respiratory quotient (RQ) will be derived from VO_2 and VCO_2.

Body composition will be determined by bioelectrical impedance analyses (BIA). Fat mass (FM) and fat free mass (FFM) will be derived. Subsequently, the percentage of FM (%FM) and FFM (%FFM) will be calculated.

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 (METs) of physical activity will be derived.

Dietary intake will be explored using three-day food records.

A blood sample will be taken for cytokine analysis.

Study design
Prospective observational

Study burden and risks
Medium study burden, no risks

Contacts

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Eligibility criteria

Age
Children (2-11 years)
Children (2-11 years)
Adolescents (12-15 years)
Adolescents (12-15 years)
Adolescents (16-17 years)
Adolescents (16-17 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 phase:	N/A
Study type:	Observational non invasive
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL
Recruitment status: Recruitment stopped

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

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Approved WMO Date:	17-07-2019
Application type:	First submission
Review commission:	METC Utrecht Huispostnr D01.343 Postbus 85500 3508 GA Utrecht 088 755 6376 metc@umcutrecht.nl

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
NTR-new	NL7657
Other	METC UMCU : METC nnb

Study results