Metabolic syndrome in adult long-term survivors of childhood cancer.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24954

Source
NTR

Health condition

Engels:
Childhood cancer survivors
Metabolic syndrome
Cardiovascular risk factors
Adrenal function
Physical activity

Nederlands:
Overlevenden van kinderkanker
Metabool syndroom
Cardiovasculaire risicofactoren
Bijnierfunctie
Lichamelijke activiteit

Sponsors and support

Primary sponsor: ErasmusMC-Sophia Children's Hospital"
Principal investigators:
Drs. M. van Waas
Dr. M.M. van den Heuvel-Eibrink
Drs. S.C.J.M.M. Neggers
Prof. Dr. R. Pieters

Source(s) of monetary or material Support: Kinderoncologie Centrum Rotterdam (KOCR) Kinderen Kankervrij (KiKa)

Intervention

Outcome measures

Primary outcome

METABOLIC SYNDROME:

1. Waist circumference (high in males when >102cm and in females when >88cm);

2. Waist/Hip ratio (high when >0.9);

3. Fasting plasma glucose (high when >=5.6 mmol/l));

4. Triglycerides (high when >=1.7 mmol/l);

5. HDL-cholesterol (high in males when <1.03 and in females when <1.3);

6. Blood pressure (high when >= 130/85).

CARDIOVASCULAR RISK FACTORS:

Imaging studies:

1. Ultrasound of carotids for measurement of intima media thickness;

2. Pulse wave velocity;

3. Ultrasound of abdominal fat (subcutaneous and preperitoneal).

Laboratory investigations:

1. Uric acid;

2. Cystatin C;

3. Lipidspectrum (total cholesterol, LDL, VLDL, HDL, free fatty acids, triglycerides, apolipoprotein A and B);

4. Thrombotic factors (Antithrombine III, Protein C and S, homocysteine, Plasminogen activator inhibitor-1 (PAI1), routine clotting parameters);

5. Pro-inflammatory markers (TNF-α, IL-6, (high sensitivity)-CRP);

6. Endocrine tests (free T4, TSH, cortisole rhythm (from saliva), IGF-1, IGF-BP-3 and BP-1, ACTH, and routine fertility screening (In females: AMH, Inhibin A en B, DHEA. If not on contraceptives: FSH, LH, oestradiol, progesterone, SHBG. In males: Inhibin B, AMH, testosterone, LH, FSH, SHBG);

7. Insulin;

8. Biomarkers for adiposity (leptin, adiponectin, adipokine);

9. Molecular analyses of genetic aberrations associated with risk factors for elevated metabolic syndrome, i.e. (P207L, D9N mutations in the lipoprotein lipase gene) peroxisome proliferative-activated receptor gamma2 (PPARγ2, aldose reductase, ABCG5 and ABCG8, SUR1, Kir 6-2 gene aberrations, Lipin1 SNPs, AMH SNPs;

10. ALAT, ASAT, gamma-GT;

11. Urine analysis: Microalbuminuria and albumin/creatinin ratio.

Secondary outcome

ADRENAL FUNCTION:

Cortisol and precursos (testosterone, DHEA, DHEAs, 17(OH)progesteron, adion) levels during Synacthen-test (ACTH stimulation test): At baseline, 30 minutes later and 60 minutes later.

PHYSICAL ACITVITY:

The five categories of health-related fitness will be investigated using a series of standardised and validated tests:

Category 1: Cardiopulmonary fitness:

The six-minute walk test, a sub-maximal test, will be used to assess cardiopulmonary fitness;

Category 2: Muscle strength and Category 4: Muscle endurance:

These categories will be measured using the following tests: Hand grip, push-ups, dynamic sit-up, back extension and standing high jump;

Category 3: Flexibility:

The following tests will be used to assess flexibility: Reaching upwards, side bending, sit & reach;

Category 5: Body composition.

Study description

Background summary

N/A

Study objective

Metabolic syndrome is more frequent in long-term survivors of childhood cancer compared with healthy controls.

Study design

All measurements will be performed on one day.

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

Patients:

1. ≥ 18 years old at January 1st in the year they will be recruited;

2. History of childhood cancer;

3. ≥5 years after cessation of therapy;

4. Treated at the Erasmus MC-Sophia Children’s Hospital.

Controls:

1. Brother or sister of the patient;

2. Friend or neighbour of the patient, of the same sex and within an age range of 5 years.

Exclusion criteria

Patients: (Partly) Treated in other country;

Controls: A history of childhood cancer.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2009
Enrollment:	1200
Type:	Anticipated

Ethics review

Positive opinion

Date:	16-03-2011
Application type:	First submission

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	NL2685
NTR-old	NTR2814
Other	METC Erasmus MC : 2009-030
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A