Metabolic syndrome and vascular damage in relation to accelerated aging in survivors of hematopoietic stem cell transplantation for hematological malignancy.

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To study in two national cohorts of HSCT survivors, treated in different time periods, the prevalence and risk factors of metabolic syndrome, endothelial dysfunction (as a sign of vascular damage) and the clinical phenotypes of accelerated aging so...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON53251

Source
ToetsingOnline

Brief title
MetVasA

Condition

- Other condition
- Vascular hypertensive disorders

Synonym
early aging (lay term: predisposition for cardiovascular disease), Metabolic syndrome, vascular disease

Health condition

metabool syndroom, veroudering

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Late effects, Metabolic syndrome, Stem cell transplantation

Outcome measures

Primary outcome

Prevalence and risk factors of metabolic syndrome (and it's components) and

endothelial dysfunction

Secondary outcome

Prevalence and risk factors of accelerated aging

Study description

Background summary

In previous studies the prevalence of both metabolic and vascular chronic health problems has been shown to be high in survivors of hematopoietic stem cell transplantation (HSCT). Co-existence of these and other aging-related conditions (*multimorbidity*) at young adult age, suggests accelerated aging occurs in HSCT survivors, potentially leading to impaired quality of life, disability and early mortality. Previous studies on these chronic health conditions in HSCT survivors only included small patient numbers and did not examine the interrelation between these health problems nor potentially modifiable lifestyle risk factors.

Study objective

To study in two national cohorts of HSCT survivors, treated in different time periods, the prevalence and risk factors of metabolic syndrome, endothelial

dysfunction (as a sign of vascular damage) and the clinical phenotypes of accelerated aging so that high risk survivor groups can be identified and preventive strategies can be developed to improve health related quality of life and prevent early mortality in HSCT survivors.

Study design

Observational prospective study

Study burden and risks

Burden is limited to time investment, but tests are non-invasive except for a blood sample, preferably fasting, (that is also needed voor care) and no risk for participants is anticipated

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)

Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)

Inclusion criteria

Survivors of hematopoietic stem cell transplantation in childhood (at age <=18 yr) for a hematological malignancy between 01-01-2002 and 01-01-2021, who are 4 years of age or older at inclusion and in follow-up in the late effects clinic of the Princess Maxima Center

Exclusion criteria

Treatment for second malignancy
No understanding of the Dutch language or illiterate

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-01-2024
Enrollment:	120
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	07-06-2023
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	28-12-2023
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	NL83998.041.23