# 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...

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| **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

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| 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

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| 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 |