# Longitudinal assessment of therapy-related early ageing in adolescent and young adult (AYA) cancer patients

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To determine markers related to early ageing and senescence in AYA cancer patients before and after systemic therapy, in order to assess treatment-related early vascular ageing and associated tumour and patient characteristics.

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Miscellaneous and site unspecified neoplasms malignant and unspecified |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON49923

**Source**
ToetsingOnline

**Brief title**
Early ageing in AYA cancer patients

### Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

**Synonym**
(non-)Hodgkin lymphoma, and cervical cancer, breast cancer, cancer: including leukemia, Ewing sarcoma, osteosarcoma, testicular cancer

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen

**Source(s) of monetary or material Support:** UMCG Kanker Researchfonds

## Intervention

**Keyword:** AYA, cancer, early ageing

## Outcome measures

### Primary outcome

Primary endpoint is change in senescence marker P16 between start of systemic therapy and one year later.

### Secondary outcome

Secondary endpoints are:

Changes in senescence-associated secretory phenotype (SASP) and vascular markers; prevalence of classical cardiovascular risk factors (lipids, BMI, glucose); tumour (treatment), patient (age, sex, pre-existent cardiometabolic status), and sociodemographic (lifestyle) factors related to the changes in senescence, SASP and cardiovascular risk factors.

# Study description

### Background summary

Compared with survivors of childhood cancer, there is sparse knowledge about the long-term morbidity and mortality of adolescent and young adult (AYA) cancer patients, who are diagnosed at age 18-39 and have an 80% chance to survive. Following cancer treatment, many cancer survivors, including those at AYA age, have an increased risk of cardiovascular disease. Early ageing has been described in paediatric and certain adult cancer survivor populations. One of the responsible mechanisms behind biological ageing is cellular senescence, characterized by a stable arrest of the cell cycle which occurs in response to stress and damage. In all organisms the number of senescent cells increases with age and senescence has been associated with age-related diseases, like atherosclerosis and Alzheimer. Early ageing as a result of intensive cancer treatment with systemic therapy and radiation may result in early

cardiovascular disease. However, information about senescence, early vascular ageing and related patient and tumour characteristics is missing for AYAs.

### Study objective

To determine markers related to early ageing and senescence in AYA cancer patients before and after systemic therapy, in order to assess treatment-related early vascular ageing and associated tumour and patient characteristics.

### Study design

Longitudinal cohort study; measurements before start of systemic therapy and one year later.

### Study burden and risks

Study measurements will be performed twice and consist of blood withdrawal and physical examination (including weight, height, waist-hip ratio, and blood pressure).

## Contacts

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## Trial sites

### Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)

## Inclusion criteria

- Aged 18-39 years at cancer diagnosis
- Having a histologically and/or cytologically confirmed cancer diagnosis, including leukemia, (non-)Hodgkin lymphoma, testicular cancer, osteosarcoma, Ewing sarcoma, breast cancer, and cervical cancer.
- Scheduled to start systemic therapy with curative intent. Allowed treatments (concurrent or sequential) are: surgery, radiotherapy, chemotherapy, antibodies.

## Exclusion criteria

- who are not able to understand the patient information letter and informed consent form
- who will be treated with immune checkpoint inhibitors or targeted therapy with inhibitors of angiogenesis
- who have been treated with systemic therapy or radiotherapy for a previous malignancy (exceptions: in situ carcinoma of the cervix or uterus and adequately treated basal and squamous cell carcinoma of the skin).

# Study design

## Design

**Study type:** Observational invasive

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

## Recruitment

NL

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| Recruitment status: | Recruiting |
| Start date (anticipated): | 10-02-2022 |

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| Enrollment: | 120 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 16-11-2021 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |
| Approved WMO Date: | 07-10-2024 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |

## 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 | NL78186.042.21 |
| Other | volgt |