# Klimop: a study on older cancer patients

Published: 14-02-2011
Last updated: 02-05-2024

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

## Summary

### ID

NL-OMON39462

**Source**
ToetsingOnline

**Brief title**
KLIMOP

### Condition

- Miscellaneous and site unspecified neoplasms benign

**Synonym**
cancer, neoplasms

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universiteit Maastricht
**Source(s) of monetary or material Support:** Interreg IV Grensregio Vlaanderen - Nederland

### Intervention

**Keyword:** cohort, geriatric oncology, prognosis, psychosocial

## Outcome measures

### Primary outcome

Wellbeing.

### Secondary outcome

Survival

Caregiver's distress

Treatment characteristics (Type of Treatment, Completion of therapy,

Complications, Complaints (e.g. fatigue, pain), Hospitalizations)

# Study description

### Background summary

There is a remarkable increase in the number of older patients with cancer. Older cancer patients represent a very heterogeneous group as within a decade of age, there is a considerable diversity in life expectancy, ability to live independently and burden of chronic diseases. Nevertheless, the knowledge of older cancer patients remains scarce. As such, little is known about the impact of cancer diagnosis and treatment on the wellbeing of older cancer patients and also the distinction between fit and frail patients is uncertain. A long term follow-up of the wellbeing of older cancer patients might provide new information which might contribute to the improvement of knowledge and care for older cancer patients.

### Study objective

The primary objective of this study is to determine the impact of a diagnosis and type of treatment of cancer, ageing and their interaction on wellbeing of older cancer patients. Furthermore, we aim to determine the different psychosocial characteristics that influence survival, depression and quality of life in older cancer patients.

### Study design

A prospective, longitudunal cohort study. Data collection will take place at inclusion, after six months of follow-up, after one year of follow-up and every

subsequent year until death or end of the study. Data will be collected through personal interviews or self-administrated quesionnaires (consisting of socio-demographic information, general health information and a comprehensive geriatric assessment, with additional questionnaires as quality of life, health locus of control and a loneliness scale), a hand-grip test, information from the medical reccord, two buccal swabs (at baseline) and through a questionnaire for the central caregiver (consisting of a depression questionnaire, coping scale and a burden scale).

### Study burden and risks

Participation in this study does not imply any risks.
Extent of the burden is limited to a yearly one-hour interview (yearly questionnaire for the caregivers).

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

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

Elderly (65 years and older)

### Inclusion criteria

OLDER AND YOUNGER CANCER PATIENTS:
- Consenting after being informed
- aged 50 years and older at time of inclusion
- Life expectancy more than 6 months (based on the judgement of the attending doctor)
- Persons who have a thorough command of Dutch
- Persons who live in the province of Limburg
- Interview within three months after cancer diagnosis;OLDER PATIENTS WITHOUT CANCER:
- Consenting after being informed
- aged 70 years and older at time of inclusion
- Life expectancy more than 6 months (based on the judgement of the attending doctor)
- Persons who have a thorough command of Dutch
- Persons who live in the province of Limburg;CENTRAL CAREGIVERS:
- Consenting after being informed
- Persons who have a thorough command of Dutch

### Exclusion criteria

OLDER AND YOUNGER CANCER PATIENTS:
- Persons with a formal diagnosis of dementia
- Persons with a previous diagnosis of invasive cancer (except non-melanoma of the skin)
- Persons too ill to participate (based in the judgement of the attending doctor);OLDER PATIENTS WITHOUT CANCER:
- Persons with a formal diagnosis of dementia
- Persons with a previous diagnosis of invasive cancer (except non-melanoma of the skin)
- Persons too ill to participate (based in the judgement of the attending doctor);CENTRAL CAREGIVERS:
no exclusion criteria

## Study design

### Design

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| Study type: | Observational non invasive |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |

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| Control: | Active |
| Primary purpose: | Other |

### Recruitment

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| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-10-2011 |
| Enrollment: | 2180 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 14-02-2011 |
| Application type: | First submission |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 05-12-2011 |
| Application type: | Amendment |
| Review commission: | MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht) |
| Approved WMO Date: | 13-02-2012 |
| Application type: | Amendment |
| Review commission: | MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht) |
| Approved WMO Date: | 09-10-2013 |
| Application type: | Amendment |
| Review commission: | MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht) |
| Approved WMO Date: | 25-11-2013 |
| Application type: | Amendment |
| Review commission: | MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht) |

# 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 | NL31414.068.10 |