Klimop: a study on older cancer patients

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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...

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

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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

Public

Universiteit Maastricht

debyelaan 1 Maastricht 6200 MD NL

Scientific

Universiteit Maastricht

debyelaan 1 Maastricht 6200 MD NL

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

Study type: Observational non invasive

Intervention model: Other

Allocation: Non-randomized controlled trial

Masking: Open (masking not used)

Control: Active Other

Recruitment

Primary purpose:

NL

Recruitment status: Recruiting Start date (anticipated): 01-10-2011

Enrollment: 2180

Type: Actual

Ethics review

Approved WMO

Date: 14-02-2011

First submission Application type:

Review commission: METC academisch ziekenhuis Maastricht/Universiteit

Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date: 05-12-2011 **Amendment** Application type:

Review commission: MEC academisch ziekenhuis Maastricht/Universiteit

Maastricht, MEC azM/UM (Maastricht)

Approved WMO

13-02-2012 Date:

Amendment Application type:

Review commission: MEC academisch ziekenhuis Maastricht/Universiteit

Maastricht, MEC azM/UM (Maastricht)

Approved WMO

09-10-2013 Date:

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