The impact of adjuvant chemotherapy on health-related quality of life in elderly resected stage III colon cancer patients

Published: 09-01-2013
Last updated: 24-04-2024

The identify the health-related quality of life of elderly patients with resected stage III colon cancer and relate the outcomes to patient and treatment characteristics (surgery alone or surgery plus adjuvant chemotherapy). Furthermore, the impact...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON39596

Source
ToetsingOnline

Brief title
Quality of life of elderly stage III colon cancer patients

Condition

- Gastrointestinal neoplasms malignant and unspecified

Synonym
Colon carcinoma (large intestine cancer)

Research involving
Human

Sponsors and support

Primary sponsor: Integraal Kankercentrum Zuid
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Adjuvant chemotherapy, Colon cancer, Elderly, Quality of life

Outcome measures

Primary outcome

Health-related quality of life

Secondary outcome

Neuropathy

Anxiety

Depression

Fatigue

Study description

Background summary

The number of elderly patients with stage III colon cancer is substantial and rising. According to the Dutch guideline, these patients should be treated with adjuvant chemotherapy after resection of the primary tumour. However, in daily practice a large proportion of these elderly patients does not receive this treatment. The efficacy of adjuvant chemotherapy on disease-free and overall survival has been established in clinical trials. However, the impact of adjuvant chemotherapy on health-related quality of life is unknown.

Study objective

The identify the health-related quality of life of elderly patients with resected stage III colon cancer and relate the outcomes to patient and treatment characteristics (surgery alone or surgery plus adjuvant chemotherapy). Furthermore, the impact of adjuvant chemotherapy on neuropathy, anxiety, depression and fatigue will also be measured.

Study design

A population-based, longitudinal study, including patients immediately after

surgery and following them for 12 months.

Study burden and risks

Participation does not pose a risk to the patient. The patient can avoid possible psychological burden by not completing the questionnaire.

Contacts

Public
Integraal Kankercentrum Zuid

Zernikestraat 29
Eindhoven 5612HZ
NL
Scientific
Integraal Kankercentrum Zuid

Zernikestraat 29
Eindhoven 5612HZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Diagnosed with primary colon cancer
TNM stage III (T1-4 N1-2 M0)
Age at time of diagnosis 70 years or older

Able to complete a Dutch questionnaire

Exclusion criteria

Patients who are not able to read or write Dutch

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-03-2013
Enrollment:	144
Type:	Actual

Ethics review

Approved WMO Date:	09-01-2013
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	10-04-2013
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	17-05-2013

Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL42739.015.12