Health related quality of life among endometrial cancer survivors, a population based study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive and genitourinary neoplasms gender unspecified NEC
Study type	Observational non invasive

Summary

ID

NL-OMON31466

Source
ToetsingOnline

Brief title
Quality of life among endometrial cancer survivors

Condition

- Reproductive and genitourinary neoplasms gender unspecified NEC

Synonym
Endometrial Cancer

Research involving
Human

Sponsors and support

Primary sponsor: Integraal Kankercentrum Zuid (IKZ)
Source(s) of monetary or material Support: IKZ betaalt onderzoek zelf

Intervention

Keyword: Endometrial cancer, Quality of life, Survivorship

Outcome measures

Primary outcome

The association between cancer treatment and quality of life (generic and

disease specific)

Secondary outcome

Patientcharacteristics (personality) in relation to quality of life and

morbidity (fatigue, anxiety, depression)

Study description

Background summary

The prevalence of cancer is rising. The increasing incidence of cancer, ageing of the population and more effective treatment strategies all contribute to this rapid increase. Based on data from the Netherlands Cancer Registry, the Dutch Cancer Society estimated that in 2005, about 1700 women were diagnosed with EC in the Netherlands, with an estimated prevalence of over 17,000, expected to increase to 25,000 in the year 2015.
Results of our previous study among endometrial cancer survivors showed that adjuvant radiotherapy was independently and negatively associated with vitality, physical and social well-being scales. Nevertheless, that study consisted of women diagnosed in the period 1994-1998, whereas afterwards treatment has changed in several hospitals in the ECR area. Rather than treating intermediate and high risk patients with radiotherapy, several gynaecologists since then started to perform pelvic lymphadenectomy, thereby administering radiotherapy only to patients with lymph-node metastases. As a result fewer patients will experience the negative sequelae associated with adjuvant EBRT. However, lymphadenectomy can result in lymfedema which are expected to have a diminishing effect on HRQL.

Study objective

The primary objective of the present study is to obtain insight into the long-term effects of EC and new treatment strategies on HRQL in a

population-based setting. Therefore, we will assess HRQL among 2 to 9 year survivors of stage I or II EC treated with surgery alone (with or without lymfadenectomy) or surgery and adjuvant EBRT, and compare them with an age-matched norm population. A secondary objective is to investigate the association between co-morbidity, life-style factors (such as smoking, physical activity, personality) and HRQL, rather than treating them as confounding variables only.

Study design

Cross-sectional observational study of 1200 EC survivors who are approached by their (formerly) treating specialists: Gynaecologists will send their (former) patients a letter to inform them about the study and a copy of the questionnaire. The letter will explain that by returning the completed questionnaire, the patient agrees to participate and consents with linkage of the outcome of the questionnaire with their disease history. If the questionnaire is not returned within 6 weeks, a reminder letter will be send.

Study burden and risks

Participation does not form a risk for the patient, psychological burden can be avoided by the patient by not completing the questionnaire.

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

Endometrial Cancer survivor, diagnosed with EC stage I or II between 1999 and 2006, not older than 85 at time of the survey

Exclusion criteria

Participants older than 85 years at time of the survey will be excluded, as previous studies pointed out that they would have difficulty in completing a self-report questionnaire without assistance because of very old age.

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):	01-05-2008
Enrollment:	1200
Type:	Actual

Ethics review

Approved WMO Date:	01-04-2008
Application type:	First submission
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	NL19760.015.07