FOllow-up among Cervical cancer sUrvivorS, perspectives from survivors, informal caregivers and health care providers (FOCUS): a cross-sectional population-based study

Published: 07-09-2018
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1) What is the variation in follow-up care practice since 2011 for cervical cancer patients?2) What physician-, patient- and informal caregiver -factors are associated with differences in follow-up care schedules? Regarding patient/ informal...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Reproductive neoplasms female malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON55762

Source
ToetsingOnline

Brief title
FOCUS

Condition

- Reproductive neoplasms female malignant and unspecified
- Cervix disorders (excl infections and inflammations)

Synonym
cervical cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg
Source(s) of monetary or material Support: NWO,KWF

Intervention

Keyword: cervical cancer, follow-up care, observational study

Outcome measures

Primary outcome

Survey health care providers

Outcomes included are provider characteristics (age, years experience, gender), hospital characteristics (hospital, type of hospital), provided follow-up schedule in the past years, reasons for deviation/compliance from guidelines, preference for future follow-up, content of follow-up consult (aim of consult, content of follow-up care consult, psychosocial functioning, late effects), and attitudes toward the guideline on follow-up care.

Study among cervical cancer patients and their informal caregiver

Measures include demographic characteristics, questions on follow-up care (schedule, preference, attitudes, satisfaction), and psychosocial characteristics (quality of life, fear of recurrence and worry, illness perceptions, self-management abilities, self-efficacy, relationship quality, dyadic coping). In addition, a feasibility study will be conducted in a subsample of participants (120 patients when 50% response). They will be asked to donate a hair sample (1,5mm) and complete additional questions about hair

care and perceived stress. Finally, data on participant's follow-up care

practice will be collected from the medical files.

Secondary outcome

NA

Study description

Background summary

Follow-up care in cancer survivors serves several purposes, including timely detection of treatable recurrences and providing support and information for psychosocial problems and late effects. In 2012, the guidelines regarding follow-up care for patients with cervical cancer were changed from 10-13 visits in 5 years to 8 visits in 2 years. Among health care providers, variation exist in follow-up care practice after this guideline was issued. We hypothesize that variation in follow-up care is influenced by the health care providers on the one hand, and by the patients and their informal caregivers (i.e. main person that provides support to the patient) on the other hand.

Study objective

1) What is the variation in follow-up care practice since 2011 for cervical cancer patients?
2) What physician-, patient- and informal caregiver -factors are associated with differences in follow-up care schedules? Regarding patient/ informal caregiver factors this relates to functioning, symptoms, needs and abilities.

Study design

We will conduct two studies to answer our research questions. The first study is a cross-sectional survey study among health care providers; the second study is a cross-sectional study among cervical cancer patients and their informal caregivers. For the second study, we will sample patients from the Netherlands Cancer Registry and collect patient-reported outcomes and data from the medical files from the patients and self-reported outcomes from the informal caregiver within PROFILES. In a subsample of patients, we additionally conduct a feasibility study for assessment of cortisol concentrations in scalp hair.

Study burden and risks

De burden of this study is the completion of the questionnaires, which takes about 20 to 60 minutes.

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

- Diagnosed with stage I-III cervical cancer between 1st January 2011 and 31st December 2016.
- Being able to complete a Dutch questionnaire.
- Being at least 18 years of age.

Exclusion criteria

- Living in nursing home.
- Unknown address.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-04-2019
Enrollment:	900
Type:	Actual

Ethics review

Approved WMO Date:	07-09-2018
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	09-01-2019
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	03-04-2019
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

Approved WMO Date:	09-09-2019
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	30-10-2019
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	01-11-2021
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL66076.028.18