Micturition, defecation and sexual well being in patients having been treated for a gynaecologic malignancy.

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1. Compare generic and pelvic-floor-specific QOL in patients who have been treated or gynaecologic cancer to that of patients without cancer attending a gynaecologist for pelvic floor symptoms.2. Examine how many and which patients receive or have…

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON30984

Source
ToetsingOnline

Brief title
PF-Gyn-Onc

Condition

- Other condition
- Reproductive neoplasms male malignant and unspecified
- Obstetric and gynaecological therapeutic procedures

Synonym
defecation and sexuality, pelvic floor symptoms, problems with micturition

Health condition

bekkenbodemklachten

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cross-sectional, gynecologic malignancy, pelvic floor, quality of life

Outcome measures

Primary outcome

Pelvic floor specific QOL

Received medical help for pelvic floor symptoms

Secondary outcome

Prognostic factors / independent factors for seeking medical help: we will

collect demographic and clinical variables to find this out.

Study description

Background summary

The prevalence of de-novo pelvic floor symptoms following surgery and/or radiotherapy because of cervical, endometrial or vulvar cancer is high. These symptoms involve micturition symptoms, defecation symptoms, and problems with sexual functioning. It has been hypothesized that these symptoms result from damage to innervation, vascularisation and anatomical relation of the visceral organs in the pelvic cavity. Next to the questionnaires we wil collect demographic and clinical data to try to find something out about prognostic or independent factors for seeking medical help.
To date, no studies exist that examine the extent to which gynaecologic cancer patients experience a comparable level of generic and pelvic-floor-specific quality of life (QOL) in comparison to patients without cancer who visit the clinic because of pelvic floor symptoms. Furthermore it is unclear how many and which cancer patients seek medical help for pelvic floor symptoms. Finally we do not know which personal, doctor-related or health-system related factors keep gynaecologic cancer patients with pelvic floor symptoms from seeking help.

Study objective

1. Compare generic and pelvic-floor-specific QOL in patients who have been treated or gynaecologic cancer to that of patients without cancer attending a gynaecologist for pelvic floor symptoms.
2. Examine how many and which patients receive or have received medical help for pelvic floor symptoms.
3. Identify the factors associated with receiving medical help.
4. Explore the factors associated with not having sought medical help because of pelvic floor symptoms following treatment of gynaecologic cancer.

Study design

We will perform a cross-sectional study in patients treated the last 10 years in the Academic Medical Centre Amsterdam (AMC) for gynaecologic cancer. We will send them after having received informed consent, questionnaires and compare these results to a clinical sample. The clinical sample consists of patients attending the gynaecologist because of micturition-, defecation- and sexual symptoms.
All patients who never sought medical help for pelvic symptoms and who have a pelvic floor symptom score comparable to scores of the clinical sample will be invited to the hospital. We will conduct a semi-structured interview with these patients to explore the reasons why they did not seek medical help because of pelvic floor symptoms. Then we will also examine the pelvis for pelvic floor problems according to the recommendations of the International Continence Society.

Study burden and risks

questionnaires: no health risk. it will take around 1 hour to fill them in.
interview: no health risk. it will take 30 to 60 minutes. the journey will be financially compensated.
Pelvic floor examination: low burden, no health risk. it will take 5-10 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

Patients treated in the last ten years in the Academic Medical Centre Amsterdam for cervical cancer, endometrial cancer or vulva cancer.

Exclusion criteria

Patients with other gynaecologic malignancies than defined in the inclusion criteria
Life expectancy of less than 3 months
Insufficient knowledge of the Dutch language
Presence of more than one primary malignancy

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2007
Enrollment:	1500
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL17850.018.07