A randomized controlled trial to evaluate the effect on pelvic floor function of pelvic physiotherapy following radical hysterectomy in early stage cervical cancer.

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To find out whether pelvic physiotherapy added to an information folder describing pelvic exercises, as is the standard post-operative policy, gives an improved pelvic related quality of life compared to patients receiving the folder only.

Ethical review	Approved WMO
Status	Pending
Health condition type	Reproductive neoplasms female malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON30897

Source
ToetsingOnline

Brief title
RCT PhT-Wertheim

Condition

- Reproductive neoplasms female malignant and unspecified
- Renal and urinary tract therapeutic procedures

Synonym
micturition and defecation problems, pelvic floor dysfunction

Research involving
Human

Sponsors and support

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

Intervention

Keyword: cervical neoplasm, pelvic floor symptoms, physiotherapy, radical hysterectomy

Outcome measures

Primary outcome

Pelvic floor related quality of life.

Secondary outcome

General quality of life.

Bladder function.

Provided hours of physiotherapy additional to the standard intervention

Health care consumption because of pelvic floor symptoms in the first year

after radical hysterectomy.

Study description

Background summary

Patients suffering from cervical cancer FIGO stage IB-IIA are treated in most cases with a radical hysterectomy. Shortly after the surgery micturition and defecation problems occur in most women, whereas in 10-80% of patients these problems remain a problem longer period after treatment. The problems vary from urinary and fecal incontinence to urinary retention and constipation. Pelvic floor related quality of life has never been investigated with validated questionnaires in this group of patients.
In literature pelvic physiotherapy is mentioned as an effective treatment or stress-incontinence. After radical prostatectomy a significant improvement in micturition frequency and severity of complaints is seen in patients treated with physiotherapy.

Study objective

To find out whether pelvic physiotherapy added to an information folder describing pelvic exercises, as is the standard post-operative policy, gives an improved pelvic related quality of life compared to patients receiving the folder only.

Study design

randomised controlled trial in which the standard post-operative management, i.e. handing out an information folder with pelvic floor exercises, is compared to the standard management plus pelvic physiotherapy.

Intervention

We will do this with a validated questionnaires. The general quality of life is measured with the questionnaire RAND-36. Furthermore bladder function is evaluated until 12 months after the surgical treatment, with a voiding diary, uroflowmetry and residue measurements with a bladder scan. The amount of hours patients need of pelvic physiotherapy or other medical treatment for pelvic floor problems are monitored.

Study burden and risks

To fill in the questionnaires, 4 times in total: burden: approximately 30 minutes every time, risks: none.
Two times extra visit to the out-patient clinic at 3 months and 12 months after the operation: burden: journey: depending on the distance between house and hospital; the visit takes approximately an hour. risks: none
Uroflowmetry: burden: the patient is asked to void once every visit on a chair above a tredmill, which records the strenght of the bladder: burden: low. risks: none.
Bladderscan for urinary residue measurement: the bladderscan is held via the abdomen aganist the bladder to measure possible residue. burden: low. risks: none.

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

cervical cancer FIGO stage IB-IIA
undergone radical hysterectomy
physically and mentally able to perform pelvic training

Exclusion criteria

Bowel and/or bladder surgery or radiotherapy in medical history

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2007
Enrollment:	72
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	NL17694.018.07