# An observational controlled study on vaginal blood flow, sexual functioning, bladder and bowel function after radiation therapy following nerve-sparing radical hysterectomy for early stage cervical cancer (FIGO IA2-IIA).

Published: 02-06-2010
Last updated: 04-05-2024

In this controlled (studygroups from P05-095 will serve as controls) observational study, the effects of radiation therapy after nerve-sparing radical hysterectomy for early stage cervical cancer on sexual function, bladder and bowel function is...

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Reproductive neoplasms female malignant and unspecified |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON41297

**Source**
ToetsingOnline

**Brief title**
Late complications of ns radical hysterectomy and radiation therapy

### Condition

- Reproductive neoplasms female malignant and unspecified
- Uterine, pelvic and broad ligament disorders
- Obstetric and gynaecological therapeutic procedures

**Synonym**
cancer of the cervix, cervical cancer

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum
**Source(s) of monetary or material Support:** SOHA subsidie van het IKW

## Intervention

**Keyword:** Cervical cancer, Post-operative radiotherapy, Sexual functioning

## Outcome measures

### Primary outcome

Sexual response measurement

To measure genital arousal, vaginal pulse amplitude (VPA) will be assessed by a vaginal photoplethysmograph. The photoplethysmograph is a menstrual tampon-sized device, containing an orange-red light source and a photocell. The light source illuminates the capillary bed of the vaginal wall and the phototransistor responds to the light backscattered by the vaginal wall and the blood circulating within it. When the signal is connected to an alternating current (AC) amplifier, vaginal pulse amplitude is measured, which reflects the phasic changes in vaginal engorgement accompanying each heartbeat, with larger amplitudes reflecting higher levels of vaginal vasocongestion. VPA is a sensitive, specific, and reliable measure of vaginal vasocongestion and is used in earlier studies that observed diminished vaginal blood flow in women with neurological damage11 and in women after radical hysterectomy4, 9. VPA will be continuously recorded during the neutral film excerpts and the erotic film excerpts.

Subjective sexual arousal and genital sensations will be assessed through 3

self-report ratings that will be collected after each neutral film and after each erotic stimulus. Participants will be asked to indicate on a seven-point Likert scale their feelings of sexual arousal, their strongest feelings of sexual arousal, and their genital sensations. Extremes of the Likert scale will be 1 *not at all*, to 7 *very strong*.

**Secondary outcome**

Questionnaires

Sexual-, bladder- and bowel complaints are assessed with questionnaires; respectively the Leiden Gynaecological questionnaire (see Appendix II) and the Gynaecological complaints questionnaire of the European Organisation for Research and Treatment of Cancer (EORTC) EORTC QLQ-CX24. More over, the general and health related quality of life is assessed by the Quality of Life questionnaire of the EORTC (EORTC QLQ-C30). These questionnaires are especially designed and validated for the assessment of the quality of life and complaints of women after treatment for gynecological malignancies.

# Study description

**Background summary**

The primary treatment for women with early-stage (FIGO IA2 - IIA) cervical cancer is radical hysterectomy with pelvic lymphadenectomy (RHL). In approximately one third of women, surgery is followed by postoperative radiation therapy. Radiation therapy is administered if the parametrium is tumor positive or the surgical margins (especially the vaginal margin) are positive. Additionally, tumor characteristics (tumor size > 40 mm, invasion depth > 15 mm and lympho-vascular space invasion) can be taken into account to advise women postoperative radiation therapy since these criteria seem to result in worse prognosis. When two out of three characteristics are met in a patient, postoperative radiation is advised, for it is known to improve the

prognosis1.
Although the results in terms of survival for low stage cervical carcinoma are reasonably good, the morbidity is still a matter of concern. Besides infertility due to the treatment, problems with miction, defecation and sexuality may effect quality of life.

With the conventional RHL, the pelvic autonomic nerves (especially the hypogastic plexus) are damaged. This leads to disrupted autonomic innervation of the bladder, rectum, and the blood vessels in the vaginal wall. Consequently, patients often experience various postoperative complaints concerning sexual functioning, bowel and bladder function. Externalbeam radiation therapy also causes sexual dysfunction and vaginal changes by chronic fibrotic changes in pelvic tissue.Studies on rectal carcinoma have shown that pre-operative radiation therapy is a significant risk factor for overall decreased sexual functioning, both in men and women. After surgery, alone or in combination with radiation therapy, several symptoms related to sexual dysfunction appeared to be the primary sources of symptom-induced distress.

A preliminary study by Pieterse et al (CME protocolno. P05.095) on nerve sparing RHL has shown outcomes of less disrupted vaginal blood flow in response to sexual stimuli in patients after nerve sparing RHL compared to conventional RHL4. Vaginal blood flow in nerve sparing RHL showed to be comparable to women after simple hysterectomy and women without hysterectomy. This study will reveal the relative impact of nerve-sparing surgery and external beam radiation on sexual functioning, bladder- and bowel function.

**Study objective**

In this controlled (studygroups from P05-095 will serve as controls) observational study, the effects of radiation therapy after nerve-sparing radical hysterectomy for early stage cervical cancer on sexual function, bladder and bowel function is assessed with the use of VPA (Vaginal Pulse Amplitude) measurement and validated questionnaires.

Hypothesis:

External beam radiation after nerve sparing radical hysterectomy will undo the positive effect of nerve-sparing surgery on of the well known sexual-, bladder- and bowel complaints as observed after treatment for early stage cervical cancer.

**Study design**

An observational study with the use of questionnaires and vaginal pulse amplitude (VPA) measuring by photoplethysmography. Women who have been treated in the past with radical hysterectomy and post-operative radiation therapy will

be approached and asked to participate. Participating women are asked to fill in three validated questionnaires: EORTC QLQ-C30 (general quality of life questionnaire for cancer patients), EORTC QLQ-CX24 (cervix carcinoma-specific quality of life questionnaire) and the Gynaecologic Leiden Questionnaire (specific questionnaire for sexual and pelvic floor symptoms). Copyright holding authorities have approved the use of the questionnaires. Furthermore, VPA will be measured to evaluate genital arousal.

The outcome of both the questionnaires as well as the VPA measurement will be compared for women after conventional radical hysterectomy without post-operative radiation therapy, after normal hysterectomy and normal controles (studygroups from P05-095).

**Study burden and risks**

For this study, the patient will visit the LUMC once. During the first part of this visit, written informed consent will be obtained. Subjects will fill out the questionnaires. Subsequently, the researcher will explain all procedures of the vaginal plethysmography in detail. She also shows and explains the devices used in the genital measurement.

The second part of the visit will consist of the experimental session with the vaginal photoplethysmography and the neutral and erotic filmfragements. After this experimental procedure, a brief exit-interview will take place.

It is possible that some parts of this study may be experienced as unpleasant, such as watching erotic film excerpts or the insertion of the measuring device. The odds of experiencing pain when inserting the measuring device is very low, due to the size of the device (shape and size are similar to a tampon) en the smoothness of the material. Further, vaginal lubricants may be used to insert the measuring device. At any moment during the experiment the experiment can be stopped if the women wants so.

# Contacts

**Public**
Leids Universitair Medisch Centrum

Albinusdreef 2 Albinusdreef 2
Leiden 2300 RC
NL
**Scientific**
Leids Universitair Medisch Centrum

Albinusdreef 2 Albinusdreef 2
Leiden 2300 RC
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

All eligible patients: have been treated for stage IA2-IIA cervical cancer with nerve-sparing radical hysterectomy with pelvine lymfeadenectomy and post-operative radiation therapy; therapy must be completed at least 12 months before; no singn of recurrance or metastatic disease when the patiënt is included; are capable of understanding, reading and writing the Dutch language; have performance status of WHO 1-2, Karnofsky >60 and are <75 years of age.

## Exclusion criteria

Women in whom intravaginal brachy-therapy and/or concomitant chemotherapy has been administered are not included.

# Study design

## Design

**Study type:** Observational invasive

| | |
|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |

| | |
|---|---|
| Primary purpose: | Treatment |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-11-2010 |
| Enrollment: | 30 |
| Type: | Actual |

## Ethics review

| | |
|---|---|
| Approved WMO Date: | 02-06-2010 |
| Application type: | First submission |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>metc-ldd@lumc.nl |

| | |
|---|---|
| Approved WMO Date: | 24-03-2015 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>metc-ldd@lumc.nl |

## 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 | NL31939.058.10 |

# Study results

| | |
|---|---|
| Date completed: | 01-10-2018 |
| Actual enrolment: | 30 |