# Sexuo-physiological functioning after cervical cancer treatment

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The assumption is that frequency of sexual dysfunction and a disturbed vaginal blood flow response will be present, in ascending order, as follows: normal controls; women after nerve-sparing radical hysterectomy; women after nerve-sparing radical...

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestopt |
| **Type aandoening** | - |
| **Onderzoekstype** | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON25666

**Bron**
Nationaal Trial Register

**Aandoening**

The primary aim of the current study is to investigate whether nerve-sparing RHL and postoperative external beam radiation therapy lead to an objectively more disturbed vaginal blood flow response during sexual stimulation than nerve-sparing RHL without external beam radiation or conventional RHL. The results will be compared to age-matched historical controls. Furthermore, the association between symptoms (on sexual function) and objective disruption of physiological functions (e.g. vaginal response to sexual stimuli) will be explored in patients with conventional RHL, nerve-sparing RHL and nerve-sparing RHL with post-operative radiation therapy.

(In Dutch: In dit gecontroleerde observationele onderzoek (met ook proefpersonen uit de protocollen met nummers P05.095 en P10.066) worden de effecten van een conventionele RHL, en zenuwsparende RHL met en zonder postoperatieve radiotherapie, bij vroeg stadium cervixcarcinoom op het seksueel functioneren geevalueerd met behulp van vaginale photoplethysmography metingen (VPA, vaginal pulse amplitude) en gevalideerde vragenlijsten.)

## Ondersteuning

**Primaire sponsor:** Leiden University Medical Center (LUMC), Leiden, The Netherlands.
**Overige ondersteuning:** SOHA IKW & KWF Kankerbestrijding & Stichting Alpe d'Huzes

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

Vaginal pulse amplitude (VPA) in response to sexual stimuli. VPA will be measured 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 (VPA) 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 damage and in women after radical hysterectomy (see publication of Pieterse et al, 2008, protocol P05.095). VPA will be recorded continuously during the experimental session. The stimulus material will be identical to the previous studies. All women will be exposed to two erotic 5.5 min film excerpts (consisting of videos depicting cunnilingus and intercourse). The erotic films will be preceded by 5 min neutral film (during which a non-erotic documentary film excerpt will be shown). The erotic film excerpts are taken from so-called women-made, female-centred erotic videotapes. VPA is sampled at 20 Hz across baseline and subsequent trails. A two-pass algorithm for automatic artefact removal (© Molenkamp Technical Support Group University of Amsterdam) is used to analyse the VPA data. After artefact deletion peak-to-trough amplitude is calculated for each remaining pulse. For each 5-minute baseline recording, a mean baseline score per subject is calculated. Mean and maximum VPA for each subject within the entire session is identified (i.e. either within erotic stimulus one or two).

# Toelichting onderzoek

### Achtergrond van het onderzoek

Changes made on 6-dec-2015

### Doel van het onderzoek

The assumption is that frequency of sexual dysfunction and a disturbed vaginal blood flow

response will be present, in ascending order, as follows: normal controls; women after nerve-sparing radical hysterectomy; women after nerve-sparing radical hysterectomy with post postoperative external beam radiation therapy and women after conventional RHL.

**Onderzoeksopzet**

At least one year after treatment for cervical cancer.

**Onderzoeksproduct en/of interventie**

An observational study will be conducted among women treated with a conventional (non-nerve sparing) radical hysterectomy for CC (P15.321). Among this group of women, the vaginal pulse amplitude (VPA) and subjective sexual arousal in response to sexual stimuli will be measured using vaginal photoplethysmography. The results obtained in the current study will be compared with the data of a group of women treated with a nerve-sparing RHL without external beam radiation (P05.095) or nerve-sparing RHL without external beam radiation (P10.066) and age-matched historical controls (from P05.095) by using a between (4 subject groups) X within (VPA) study design. The study will be conducted multicenter: The photoplethysmography will be performed at the LUMC. Also, the study is coordinated at the LUMC. Participants are recruited at the AMC.

# Contactpersonen

## Publiek

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## Wetenschappelijk

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Eligible women are: treated for early stage cervical cancer (FIGO IA2 – IIA) at least 12 months before; treated with conventional radical hysterectomy with pelvic lymphadenectomy using the Okabayashi method (RHL-WO) at the AMC; younger than 52 years old; pre-menopausal; and have a performance status of WHO 1-2 and Karnofsky >60. Women are selected on menopausal status, because this can have influence on the vaginal perfusion response. In case eligible women of 40-52 years old that menstruated regularly before the RHL-WO, and report menopausal complaints, LH and FSH-values are measured by taking a blood sample so that their menopausal status could be established.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria are: signs of recurrent or metastatic cervical cancer after 1 year; treatment with external beam radiation therapy, intravaginal brachytherapy and/or concomitant chemotherapy; removed ovaries during surgery; not being able to understand, read and write the Dutch language; and being pregnant. Use of medication and hormonal substitutes is registered.

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Niet-gerandomiseerd |
| Blindering: | Open / niet geblindeerd |
| Controle: | Actieve controle groep |

## Deelname

Nederland
Status: Werving gestopt

| | |
|---|---|
| (Verwachte) startdatum: | 01-01-2005 |
| Aantal proefpersonen: | 120 |
| Type: | Werkelijke startdatum |

### Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

## Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 04-09-2015 |
| Soort: | Eerste indiening |

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 42343
Bron: ToetsingOnline
Titel:

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

| Register | ID |
|---|---|
| NTR-new | NL5229 |
| NTR-old | NTR5453 |
| CCMO | NL54662.058.15 |
| OMON | NL-OMON42343 |

## Resultaten