Sexuo-physiological functioning after cervical cancer treatment

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25666

Source
Nationaal Trial Register

Health condition

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.)

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC), Leiden, The Netherlands.
Source(s) of monetary or material Support: SOHA IKW & KWF Kankerbestrijding & Stichting Alpe d’Huzes

Intervention

Outcome measures

Primary outcome

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).

Secondary outcome

Subjective sexual arousal in response to sexual stimuli. Subjective sexual arousal 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. Extremes of the Likert scale will be 1 “not at all”, to 7 “very strong”. Furthermore, sexual complaints will be assessed using the Leiden Questionnaire (LQ), Gynaecological symptom module questionnaire of the European Organisation for Research and Treatment of Cancer (EORTC) EORTC QLQ-CX24, and the Female Sexual Function Index (FSFI). General health related quality of life is assessed by the Quality of Life core questionnaire of the EORTC (EORTC QLQ-C30). The Female Sexual Distress Scale (FSDS) will measure sexually related personal distress. The womens’ satisfaction with their sexual relationship was evaluated using the Golombok Rust Inventory of Sexual Satisfaction (GRISS). The presence of anxiety and depressive states will be assessed using the Hospital Anxiety and Depression Scale (HADS). Data obtained will be registered and analyzed using SPSS.

Study description

Background summary

Changes made on 6-dec-2015

Study objective

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.

Study design

At least one year after treatment for cervical cancer.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2005
Enrollment:	120
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	04-09-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 42343
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results