PORTEC-4: Randomised trial investigating the role and optimal dose of vaginal brachytherapy for endometrial cancer.

Gepubliceerd: 29-01-2012 Laatst bijgewerkt: 18-08-2022

Although vaginal brachytherapy reduces vaginal recurrence compared to observation after surgery for endometrial cancers with high-intermediate risk features, ultimate 5-year vaginal control including treatment for relapse will be similar, and a...

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29071

Bron
NTR

Verkorte titel
PORTEC-4

Aandoening

Endometrial carcinoma

Keywords: Radiotherapy, vaginal brachytherapy, randomised trial, adjuvant treatment, endometrial cancer, risk factors

Ondersteuning

Primaire sponsor: Leiden University Medical Center
Overige ondersteuning: Dutch Cancer Society (UL2011-5336)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary endpoint: Vaginal recurrence;
Second primary endpoint: 5-year vaginal control including treatment for relapse.

Toelichting onderzoek

Achtergrond van het onderzoek

Background:

Endometrial cancer (EC) is the most common gynaecological cancer. Surgery (hysterectomy and oophorectomy) is the primary treatment. Previous randomized trials, among which the PORTEC-1 trial, have shown that postoperative radiation therapy (RT) significantly reduces the risk of vaginal and pelvic recurrence from 14 to 4%, but without difference in overall survival. Most (75%) local recurrences are located in the proximal vagina, and can effectively be treated with RT at the time of recurrence. After completion of the PORTEC-1 trial, the indication for RT has become limited to patients with risk factors. The PORTEC-2 trial has shown that for these patients, vaginal brachytherapy alone is highly effective in preventing vaginal recurrence, with less side effects and better quality of life than external beam pelvic radiotherapy. However, treating all patients with risk factors with brachytherapy is still significant overtreatment. If a watchful waiting policy would be adopted, with prompt treatment in case of vaginal relapse, the eventual local control (including treatment for relapse) might be very similar to the local control after adjuvant brachytherapy. A range of published brachytherapy dose schedules has equal efficacy, and the rate of vaginal atrophy changes in PORTEC-2 suggests that the standard dose schedule of 21 Gy in 3 fractions of 7 Gy could be compared to a lower dose schedule.

Objectives and Design:

In this multicenter trial, patients with endometrioid type endometrial adenocarcinoma with high-intermediate risk features were randomised (2:1) to vaginal brachytherapy (standard arm) and observation (experimental arm). Patients in the vaginal brachytherapy arm were 1:1 randomized to brachytherapy dose 21 Gy HDR in 3 fractions of 7 Gy each (standard dose) and brachytherapy dose 15 Gy HDR at 5 mm depth, in 3 fractions of 5 Gy (lower dose).

However, the study was stopped in this design from 20 September 2015 onwards, and

continued after a major design change in June 2016 as PORTEC-4a with a new design, with new METC number and approval - see the PORTEC-4a trial record NL5602 (NTR5841)

Doel van het onderzoek

Although vaginal brachytherapy reduces vaginal recurrence compared to observation after surgery for endometrial cancers with high-intermediate risk features, ultimate 5-year vaginal control including treatment for relapse will be similar, and a lower dose of vaginal brachytherapy (15 Gy vs 21 Gy in 3 fractions) has similar efficiacy with reduced vaginal side effects.

Onderzoeksopzet

5-year rates of recurrence, vaginal control, survival, quality of life, vaginal toxicity.

Evaluation at 6-months invervals.

Onderzoeksproduct en/of interventie

Patients are randomised (2:1) to receive vaginal brachytherapy (standard arm), or observation after surgery (experimental arm); patients in the vaginal brachytherapy group are randomized 1:1 to standard dose (21 Gy in 3 Gy fractions), or reduced dose (15 Gy in 3 fractions).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Histologically confirmed endometrioid type endometrial carcinoma, FIGO 2009 stage I, with one of the following combinations of substage, age, and grade:

A. Stage IA, age 60 years or older and grade 3;

B. Stage IB, age 60 years or older and grade 1 or 2;

C. Stage IB, any age, grade 1-2 with documented lymph-vascular space invasion (LVSI).

2. Surgery consisted of Total Abdominal or Laparoscopic Hysterectomy and Bilateral Salpingo-oophorectomy (TH-BSO);

3. WHO-performance status 0-2;

4. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Any other stage and type of endometrial carcinoma;

2. Histological types papillary serous carcinoma or clear cell carcinoma;

3. Uterine sarcoma (including carcinosarcoma);

4. Previous malignancy (except for non-melanomatous skin cancer) < 5 yrs;

5. Previous pelvic radiotherapy;

6. Interval between the operation and start of radiotherapy exceeding 8 weeks.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-05-2012
Aantal proefpersonen:	500
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
See PORTEC-4a

Ethische beoordeling

Positief advies

Datum:	29-01-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3114
NTR-old	NTR3263
Ander register	KWF / METC LUMC : UL2011-5336 / P11.185;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
PORTEC-1 trial: Creutzberg CL et al, Lancet 355:1404-1411, 2000
PORTEC-2 trial: Nout RA et al, Lancet 375:816-823, 2010
Quality of life: Nout RA et al, J Clin Oncol 27:3547-3556, 2009