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

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29071

Source
NTR

Brief title
PORTEC-4

Health condition

Endometrial carcinoma

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

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: Dutch Cancer Society (UL2011-5336)

Intervention

Outcome measures

Primary outcome

Primary endpoint: Vaginal recurrence;

Second primary endpoint: 5-year vaginal control including treatment for relapse.

Secondary outcome

1. Vaginal toxicity;

2. Quality of life;

3. Pelvic recurrence;

4. Overall survival.

Study description

Background summary

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)

Study objective

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.

Study design

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

Evaluation at 6-months invervals.

Intervention

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).

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-05-2012
Enrollment:	500
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
See PORTEC-4a

Ethics review

Positive opinion

Date:	29-01-2012
Application type:	First submission

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

Study results

Summary results
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