

# **PORTEC-2: Post-Operative Radiation Therapy for Endometrial Carcinoma - a multicentre randomised phase III trial comparing external beam radiation and vaginal brachytherapy**

<b>Submission date</b> 20/12/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 20/12/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/02/2020	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## **Contact information**

**Type(s)**  
Scientific

**Contact name**  
Dr C.L. Creutzberg

**Contact details**  
Leiden University Medical Centre  
Department of Clinical Oncology  
P.O. Box 9600  
Leiden  
Netherlands  
2300 RC  
+31 (0)71 526 3027  
c.l.creutzberg@lumc.nl

## **Additional identifiers**

**ClinicalTrials.gov (NCT)**  
NCT00376844

**Protocol serial number**  
NTR332; CKTO 2001-04; LUMC P01.146

# Study information

## Scientific Title

PORTEC-2: Post-Operative Radiation Therapy for Endometrial Carcinoma - a multicentre randomised phase III trial comparing external beam radiation and vaginal brachytherapy

## Acronym

PORTEC-2

## Study objectives

Vaginal brachytherapy, as compared to external beam pelvic radiotherapy, will provide equal 5-year vaginal control and overall survival, with less treatment related morbidity and better quality of life.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Received from the local medical ethics committee

## Study design

Multicentre, randomised, active controlled, parallel group trial

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Endometrial carcinoma

## Interventions

Patients are randomised to receive external beam pelvic radiotherapy (standard arm: 46 Gy in 2 Gy fractions in 5 weeks) or vaginal brachytherapy (study arm: HDR 21 Gy in 3 fractions of 7 Gy, each 1 week apart; or MDR 28 Gy in one session; or LDR 30 Gy in one session).

## Intervention Type

Other

## Phase

Not Specified

## Primary outcome(s)

5-year actuarial vaginal relapse

## Key secondary outcome(s)

1. 5-year overall survival and cancer-specific survival
2. Quality of life and treatment related morbidity

3. 5-year rates of pelvic and distant relapse
4. Local control and survival after relapse

**Completion date**

01/09/2006

## Eligibility

**Key inclusion criteria**

1. Endometrial carcinoma, with one of the following combinations of postoperative FIGO stage and age:
  - 1.1. Stage 1C grade 1 or 2 and age 60 or over
  - 1.2. Stage 1B grade 3 and age 60 or over
  - 1.3. Stage 2A, any age, grade 1 or 2
  - 1.4. Stage 2A, any age, grade 3 with less than half myometrial invasion
2. Surgery consisted of a total abdominal hysterectomy and bilateral salpingo-oophorectomy (TAH-BSO)
3. Histologically proven adenocarcinoma; grade of differentiation determined according to the Federation of Obstetricians and Gynaecologists (FIGO)/Armed Forces Institute of Pathology (AFIP) criteria; depth of myometrial invasion documented
4. World Health Organization (WHO) performance status 0 - 2
5. Written informed consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Senior

**Sex**

Female

**Total final enrolment**

427

**Key exclusion criteria**

1. One of the following combinations of FIGO stage and age:
  - 1.1. Stage 2B, 3 or 4
  - 1.2. Stage 2A and grade 3 with 50% or greater myometrial invasion
  - 1.3. Stage 1A or 1B grade 1 or 2
  - 1.4. Stage 1B grade 3 and age below 60
  - 1.5. Stage 1C grade 1 or 2 and age below 60
  - 1.6. Stage 1C grade 3, any age
2. Histological subtypes papillary serous carcinoma or clear cell carcinoma
3. Routine staging lymphadenectomy
4. Interval between the operation and start of radiotherapy exceeding 8 weeks
5. History of any previous malignancy, except for basal cell carcinoma of the skin

6. Previous pelvic radiotherapy
7. Hormonal therapy or chemotherapy for this tumour
8. Prior diagnosis of Crohn's disease or ulcerative colitis

**Date of first enrolment**

01/06/2002

**Date of final enrolment**

01/09/2006

## Locations

**Countries of recruitment**

Netherlands

**Study participating centre**

**Leiden University Medical Centre**

Leiden

Netherlands

2300 RC

## Sponsor information

**Organisation**

Leiden University Medical Centre (LUMC) (Netherlands)

**ROR**

<https://ror.org/027bh9e22>

## Funder(s)

**Funder type**

Charity

**Funder Name**

KWF Kankerbestrijding

**Alternative Name(s)**

Dutch Cancer Society, Dutch Cancer Society (KWF Kankerbestrijding), KWF, DCS

**Funding Body Type**

Private sector organisation

## Funding Body Subtype

Other non-profit organizations

## Location

Netherlands

## Funder Name

Commission for Medical Applied Research (Commissie voor Klinisch Toegepast Onderzoek [CKTO]) (Netherlands)

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	20/07/2009		Yes	No
<a href="#">Results article</a>	results	06/03/2010		Yes	No
<a href="#">Results article</a>	results	01/07/2012		Yes	No
<a href="#">Results article</a>	results	15/11/2015	14/02/2020	Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes