ISRCTN16228756 https://doi.org/10.1186/ISRCTN16228756

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

Submission date
20/12/2005

Recruitment status
No longer recruiting

Registration date
20/12/2005

Overall study status
Completed

Last Edited
14/02/2020

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.clinicalresearch.nl/portec2

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00376844

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
5-year actuarial vaginal relapse

Secondary outcome measures
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

Overall study start date
01/06/2002

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

Age group
Senior

Sex

Female

Target number of participants
400

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 IA or IB 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 IC 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)

Sponsor details
Albinusdreef 2
P.O. Box 9600
Leiden
Netherlands
2300 RC

Sponsor type
University/education

Website
http://www.lumc.nl/

ROR
https://ror.org/027bh9e22

Funder(s)

Funder type
Charity

Funder Name
KWF Kankerbestrijding

Alternative Name(s)
The Dutch Cancer Society, Koningin Wilhelmina Fonds, DCS, KWF

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/07/2009		Yes	No
Results article	results	06/03/2010		Yes	No
Results article	results	01/07/2012		Yes	No
Results article	results	15/11/2015	14/02/2020	Yes	No