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Randomised phase III trial comparing concurrent chemoradiation and adjuvant chemotherapy with pelvic radiation alone in high risk and advanced stage endometrial carcinoma

Submission date	Recruitment status	[_] Prospectively registered
28/09/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/09/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/04/2022	Cancer	

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-trial-looking-at-radiotherapy-and-chemotherapy-after-surgery-in-women-with-womb-cancer

Study website
http://www.clinicalresearch.nl/portec3/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2007-004917-33

IRAS number

ClinicalTrials.gov number
NCT00411138

Secondary identifying numbers
CKTO 2006-04; LUMC P06.031

Study information

Scientific Title
Randomised phase III trial comparing concurrent chemoradiation and adjuvant chemotherapy with pelvic radiation alone in high risk and advanced stage endometrial carcinoma: PORTEC-3

Acronym
PORTEC-3

Study objectives
The addition of concurrent and adjuvant chemotherapy to postoperative radiation therapy will increase five year overall survival and failure-free survival of patients with high-risk and advanced stage endometrial carcinoma.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)

Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Endometrial carcinoma

Interventions
Patients are randomised (1:1) to receive external beam pelvic radiotherapy (standard arm: 48.6 Gy in 1.8 Gy fractions), or pelvic radiotherapy with concurrent chemotherapy (two cycles of cisplatin) followed by adjuvant chemotherapy (four cycles of carboplatin and paclitaxel; experimental arm).

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Cisplatin, carboplatin, paclitaxel

Primary outcome measure
1. Five year actuarial overall suvival
2. Five year actuarial failure-free survival (with failure defined as relapse or death due to endometrial carcinoma or to treatment complications)

Secondary outcome measures
1. Quality of life
2. Severe treatment related morbidity
3. Five year rates of vaginal, pelvic and distant relapse

Overall study start date
15/09/2006

Completion date
01/01/2020

Eligibility

Key inclusion criteria
1. Histologically confirmed endometrial carcinoma, with one of the following postoperative International Federation of Gynecology and Obstetrics (FIGO 1988) stages and grade:
1.1. Stage IB grade 3 with documented Lymphatic Vascular Space Invasion (LVSI)
1.2. Stage 1C grade 3
1.3. Stage II grade 3
1.4. Stage IIIA or IIIC (IIIA based on peritoneal cytology alone is only eligible if grade 3)
1.5. Stage IB or IC, stage II or stage III with serous or clear cell histology

2. World Health Organisation (WHO) performance status zero to two
3. White Blood Cells (WBC) more than or equal to 3.0 x 10^9/L
4. Platelets more than or equal to 100 x 10^9/L
5. Bilirubin less than or equal to 1.5 x Upper Normalised Limit (UNL)
6. Aspartate Aminotransferase (ASAT)/Alanine Aminotreansferase (ALAT) less than or equal to 2.5 x UNL
7. Written informed consent

As of 11/02/2011 the criteria has been updated to also include the new FIGO 2009 staging system:
Histologically confirmed endometrial carcinoma, with one of the following postoperative FIGO 2009 stages and grade:
1. Stage IA with myometrial invasion, grade 3 with documented LVSI
2. Stage IB grade 3
3. Stage II
4. Stage IIIA or IIIC; or IIIB if parametrial invasion only
5. Stage IA (with myometrial invasion), IB, II, or III with serous or clear cell histology

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
500

Total final enrolment
686

Key exclusion criteria
1. Previous malignancy, except for basal cell carcinoma of the skin, less than ten years
2. Previous pelvic radiotherapy
3. Hormonal therapy or chemotherapy for this tumor
4. Macroscopic stage IIB for which Wertheim type hysterectomy
5. Prior diagnosis of Crohn's disease or ulcerative colitis
6. Residual macroscopic tumor after surgery
7. Creatinine clearance less than or equal to 60 ml/min (calculated according to Cockroft) or less than or equal to 50 ml/min (EthyleneDiamineTetraacetic Acid [EDTA] clearance, or measured creatinine clearance)
8. Impaired cardiac function, prohibiting the infusion of large amounts of fluid during cisplatin therapy
9. Peripheral Neuropathy more than or equal to grade two

Date of first enrolment
15/09/2006

Date of final enrolment

20/12/2013

Locations

Countries of recruitment
Australia

Canada

France

Italy

Netherlands

New Zealand

United Kingdom

Study participating centre
Leiden University Medical Center (LUMC)
Leiden
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2300 RC

Sponsor information

Organisation
Leiden University Medical Center (LUMC) (The Netherlands)

Sponsor details
Department of Clinical Oncology
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05xvt9f17

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
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
National Health and Medical Research Council

Alternative Name(s)
NHMRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Australia

Funder Name
Cancer Australia

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Australia

Funder Name
Canadian Cancer Society Research Institute

Alternative Name(s)
l'Institut de recherche de la Société canadienne du cancer, CCSRI, IRSCC

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
Canada

Funder Name
Agenzia Italiana del Farmaco, Ministero della Salute

Alternative Name(s)
Italian Medicines Agency, Agenzia Italiana del Farmaco, Italian Medicines Agency, Ministry of Health, AIFA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Italy

Results and Publications

Publication and dissemination plan
Follow-up information is needed for at least 5 years for all randomised patients, and thus follow-up, queries and completion of CRF are ongoing and the timing of final analysis of the primary endpoint of OS will not be reached before late 2017 or (most likely) in 2018. We will publish 2-year results on toxicity and quality of life in 2016.

Intention to publish date
01/01/2018

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	01/08/2016		Yes	No
Results article	results	01/02/2018		Yes	No
Results article	results	01/09/2019	30/07/2019	Yes	No
Results article	results of correlation between molecular subgroup and prognosis	10/10/2020	05/03/2021	Yes	No
Plain English results			24/03/2022	No	Yes
Results article	Radiotherapy Quality Assurance	11/12/2021	21/04/2022	Yes	No