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Simultaneous boost intensity-modulated radiotherapy for locally advanced cervical cancer

Submission date	Recruitment status	[ ] Prospectively registered
21/10/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/10/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/09/2019	Cancer	[ ] Record updated in last year

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-intensity-modulated-radiotherapy-imrt-to-treat-cancer-cervix-depict

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT01230996

Protocol serial number
7896

Study information

Scientific Title
A phase I/II, multicentre dose escalation study of simultaneous boost intensity-modulated radiotherapy for locally advanced cervical cancer

Acronym
DEPICT

Study objectives
A dose escalation study of simultaneous boost intensity-modulated radiotherapy for locally advanced cervical cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Riverside Research Ethics Committee, 07/12/2009, ref: 09/H0706/90

Study design
Multicentre non-randomised interventional phase I/II treatment trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic: Gynaecological Cancer; Disease: Cervix

Interventions
Brief summary:
This will be the first study to assess the clinical feasibility of dose escalation with simultaneous integrated boost intensity-modulated radiotherapy for patients with locally advanced cervical cancer. Following screening to confirm eligibility patients will commence a six week treatment period. After this, patients will be followed up by visits to clinic every 3 months for a period of 24 months (2 years). End of study is defined as 24 months after treatment. Patients will be followed up for a minimum of 5 years (as per local policy) after treatment.

Study design:
Primary Purpose: Treatment
Study Phase: Phase I/II
Intervention Model: Single Group Assignment
Number of Arms: One
Masking: Open Label
Allocation: N/A
Enrolment: 44

Interventions:
Integrated boost intensity-modulated radiotherapy (IMRT) once a day for treatment (Monday to Friday) over 6 weeks. Each treatment lasts for approximately 10 minutes. Chemotherapy: weekly cisplatin
Sequencing: Radiotherapy 30 minutes - one hour after completing cisplatin infusion. Weekly cisplatin for up to 5 weeks concomitantly with radiotherapy
Dose: Cisplatin 40 mg/m^2 (maximum 75 mg) in 1 litre of normal saline over an hour.
Pre-hydration and post-hydration: according to local practice. Magnesium supplement is recommended in the hydration.

Follow up length: 24 months
Study entry: registration only

Intervention Type
Mixed

Primary outcome(s)
Severe gastrointestinal toxicity assessed according to Common Terminology for Adverse Event Criteria (CTCAE) v 3.0, measured within six months of completing radiotherapy

Key secondary outcome(s))
1. Objective tumour response rate, measured at 6 months
2. Two year local control rate, measured at 2 years

Completion date
31/07/2016

Eligibility

Key inclusion criteria
1. Histologically confirmed squamous cell carcinoma, adenocarcinoma or poorly differentiated carcinoma of the cervix
2. International Federation of Gynecology and Obstetrics (FIGO) stage IIB - IVA (any pelvic nodal status) and FIGO stage 1B2 and IIA with pelvic nodal involvement
3. Measurable disease on magnetic resonance imaging (MRI)
4. Aged greater than 18 years (no upper limit), either sex
5. World Health Organisation (WHO) performance status 0 or 1
6. Adequate renal function with ethylenediaminetetraacetic acid (EDTA) clearance greater than 55 ml/min
7. Adequate liver function, as defined by alanine aminotransferase (ALT) or aspartate aminotransferase (AST) less than 2.5 upper limit of normal (ULN), and bilirubin less than 1.25 ULN
8. Adequate bone marrow function, defined by white cell count (WCC) greater than 3.0 x 10^9 /litre, neutrophils greater than 1.5 x 10^9/litre and platelets greater than 100 x 10^9 /litre
9. Able to understand and give written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Evidence of common iliac or para-aortic nodal involvement, or distant metastases
2. Previous history of cancer except skin tumour
3. Previous pelvic radiotherapy or surgery other than toparoscopic node disection
4. Previous history of pelvic adhesions, inflammatory bowel disease, pelvic inflammatory disease or diabetes mellitus
5. Previous history of pelvic adhesions, inflammatory bowel disease, pelvic inflammatory disease or diabetes mellitus
6. Females of childbearing potential must have a negative pregnancy test within 7 days prior to being registered for protocol therapy if required. Acceptable contraception should be used such as barrier or hormonal methods.
7. Females must not be pregnant or breastfeeding

Date of first enrolment
22/07/2010

Date of final enrolment
31/07/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Barts and The London NHS Trust
London
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Sponsor information

Organisation
Barts and The London NHS Trust (UK)

ROR
https://ror.org/00b31g692

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK) - Clinical Trials Advisory and Awards Committee (CTAAC) grant (ref: C7925/A10990)

Results and Publications

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?
HRA research summary			28/06/2023	No	No