

Simultaneous boost intensity-modulated radiotherapy for locally advanced cervical cancer

Submission date 21/10/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/10/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/09/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT01230996

Secondary identifying numbers

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

Secondary study design

Non randomised study

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

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/m² (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 measure

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

Secondary outcome measures

1. Objective tumour response rate, measured at 6 months
2. Two year local control rate, measured at 2 years

Overall study start date

22/07/2010

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 3.0×10^9 /litre, neutrophils greater than 1.5×10^9 /litre and platelets greater than 100×10^9 /litre
9. Able to understand and give written informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned sample size: 44; UK sample size: 44

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 laparoscopic node dissection
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**

England

United Kingdom

Study participating centre
Barts and The London NHS Trust
London
United Kingdom
EC1M 6BQ

Sponsor information

Organisation

Barts and The London NHS Trust (UK)

Sponsor details

School of Medicine and Dentistry
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United Kingdom
E1 8PR

Sponsor type

Hospital/treatment centre

Website

<http://www.bartsandthelondon.nhs.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

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?
HRA research summary			28/06/2023	No	No