

Simultaneous boost intensity-modulated radiotherapy for locally advanced cervical cancer

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

Primary study design

Interventional

Study design

Multicentre non-randomised interventional phase I/II treatment trial

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/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(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 10⁹ /litre, neutrophils greater than 1.5 x 10⁹/litre and platelets greater than 100 x 10⁹ /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 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**

United Kingdom

England

Study participating centre

Barts and The London NHS Trust

London

United Kingdom

EC1M 6BQ

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