

Investigating the timing of high dose rate (HDR) brachytherapy with external beam radiation therapy (EBRT) in intermediate and high risk localised prostate cancer patients and its effects on toxicity and quality of life

Submission date 09/04/2015	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 10/04/2015	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 11/12/2018	Condition category Cancer	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

<http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-to-find-the-best-timing-for-brachytherapy-and-external-radiotherapy-for-prostate-cancer>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

ARCTU-SUH-001

Study information

Scientific Title

A randomised controlled feasibility trial to investigate the timing of HDR Brachytherapy with EBRT in intermediate and high risk localised prostate cancer patients and its effects on toxicity and quality of life

Acronym

THEPCA

Study objectives

Prospective assessment of genitourinary toxicities according to the treatment sequence of HDR brachytherapy and EBRT.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Ethics, 22/09/2014, ref: 14/LO/1662

Primary study design

Interventional

Study design

Randomised controlled two-arm trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Prostate cancer

Interventions

This will be a randomised two arm trial in which intermediate and high risk prostate cancer patients treated with both HDR brachytherapy and EBRT.

In Arm A: Patients receive HDR Brachytherapy before EBRT

In Arm B (control): Patients receive EBRT before HDR Brachytherapy. The assessment of the acute and late toxicities at various time points will be carried out. The treatment should start within 3 months from the randomisation date.

Intervention Type

Mixed

Primary outcome(s)

Prospective assessment of genitourinary toxicities according to the treatment sequence of HDR Brachytherapy and EBRT.

Key secondary outcome(s)

1. Treatment outcomes including biochemical response and survival
2. Prospective assessment of gastrointestinal toxicities according to the treatment sequence of

HDR brachytherapy and EBRT

3. Assessment of Radiotherapy Planning Challenges including Image Guided Radiotherapy

Completion date

01/01/2017

Eligibility

Key inclusion criteria

1. Patient age >18 years
2. Histologically diagnosed Prostate cancer, stages T1b-T3bN0M0
3. Any Gleason score
4. Any PSA level
5. Patient able to consent and fill in the questionnaires

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Male

Key exclusion criteria

1. Previous TURP/HoLEP Laser Prostatectomy
2. Any Metastatic Disease
3. IPSS>20
4. Pubic arch interference
5. Lithotomy position
6. If Anaesthesia is not possible
7. Rectal fistula
8. Prior pelvic radiotherapy

Date of first enrolment

25/01/2015

Date of final enrolment

01/01/2017

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Southend University Hospital NHS Foundation Trust

Prittlewell Chase

Westcliff on Sea

United Kingdom

SS0 0RY

Sponsor information

Organisation

Southend University Hospital NHS Foundation Trust

ROR

<https://ror.org/05fa42p74>

Funder(s)

Funder type

Not defined

Funder Name

Southend University Hospital NHS Foundation Trust (UK)

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?
Protocol article	protocol	29/04/2015		Yes	No
HRA research summary			28/06/2023	No	No