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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 [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 10/04/2015	**Overall study status** Completed	
Last Edited 11/12/2018	**Condition category** Cancer	

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled two-arm trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
22/01/2015

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

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
50

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
England

United Kingdom

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

Sponsor details
Prittlewell Chase, Westcliff-on-Sea, Essex SS0 0RY
Southend
England
United Kingdom
SS0 0RY

Sponsor type
Hospital/treatment centre

Website
http://www.southend.nhs.uk/

ROR

https://ror.org/05fa42p74

Funder(s)

Funder type
Not defined

Funder Name
Southend University Hospital NHS Foundation Trust (UK)

Results and Publications

Publication and dissemination plan

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