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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

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| **Submission date**<br>09/04/2015 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[X] Protocol<br>[_] Statistical analysis plan<br>[_] Results<br>[_] Individual participant data<br>[_] Record updated in last year |
| **Registration date**<br>10/04/2015 | **Overall study status**<br>Completed | |
| **Last Edited**<br>11/12/2018 | **Condition category**<br>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

**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

### Study design
Randomised controlled two-arm trial

### Primary study design
Interventional

### 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 |