IUC26669-9

The LDR BURST Trial – A Randomised Comparison of Toxicity Outcomes Following LDR Brachytherapy vs 5-Fraction SBRT With a Rectal Spacer for Localised Prostate Cancer

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WORLD'S FIRST RANDOMISED COMPARISON WITH RECTAL SPACER GEL

BACKGROUND

There is a lack of randomised evidence comparing the side effects of LDR brachytherapy and modern EBRT in localised prostate cancer.

For over 30 years, LDR brachytherapy has delivered excellent survival and toxicity outcomes. During this time EBRT has migrated from the conventional to the ultra-hypofractionated era. Advances in imaging, delivery and rectal spacer gels support dose escalation. Level 1 evidence is however required to support the mounting dosimetric and clinical evidence for rectal spacer gels.

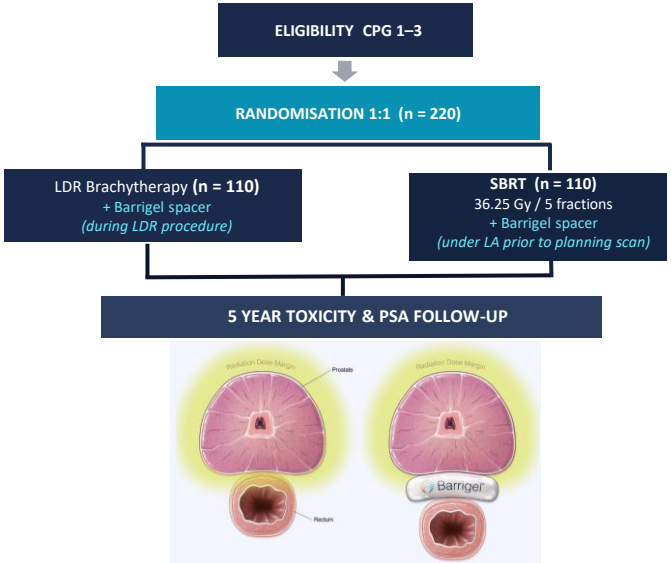
The LDR BURST Trial (NCT07210502) aims to address this evidence gap by directly comparing the toxicity profiles of LDR brachytherapy and SBRT, with both arms receiving a rectal spacer gel.

WHY THIS MATTERS

- First Level 1 evidence for rectal spacer in LDR Brachytherapy vs SBRT
- Direct toxicity comparison to guide treatment selection
- Patient-centred outcomes using validated PROMs
- Informs shared decision-making for CPG 1–3 prostate cancer

Parallel-group RCT | 220 patients | 1:1 allocation

TRIAL DESIGN



ENDPOINTS

Primary:
Minimally important difference in EPIC-26 (patient-reported outcome measures evaluating urinary incontinence, urinary irritative/obstructive, bowel and sexual domains)

Secondary:
Additional validated PROMs (IPSS, IIEF-5, Vaizey Incontinence Score), CTCAE toxicity grading, PSA monitoring and survival outcomes

KEY ELIGIBILITY

Inclusion: Localised prostate cancer; CPG 1–3
Key exclusions: Gleason 4+3; clinical indication or need for androgen deprivation therapy (ADT), PSA > 20

KEY FEATURES

- HRA & HCRW approved
- Multicentre: UK & European centres invited

OPEN TO RECRUITMENT

NCT07210502
www.trialburst.org

IUCS • Guildford • September 2026

REFERENCES
Hayhurst W, et al. BMJ Open. 2026;16:e114633
LDR BURST Trial: https://www.trialburst.org/