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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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Introduction

To date there is a lack of randomised evidence comparing the side effects of low dose rate (LDR) brachytherapy and external beam radiotherapy (EBRT) in localised prostate cancer. For more than 30 years, LDR brachytherapy has delivered excellent treatment outcomes. During this time EBRT has migrated from the conventional to the ultra-hypofractionated era. The landmark PACE-B trial demonstrated excellent short-term efficacy and tolerability of the 5-fraction ultra-hypofractionated treatment compared with the 20-fraction regimen.

Advances in imaging, treatment delivery, and the development of modern adjuncts, such as rectal spacer gels, have given clinicians greater confidence in dose escalation. Level one 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 gap, by comparing the toxicity profiles of LDR brachytherapy to stereotactic body radiotherapy treatment (SBRT) with a rectal spacer gel, in men with Cambridge Prognostic Group 1-3 prostate cancer.

Methods

This parallel group randomised trial will allocate 220 patients on a 1:1 basis to either LDR brachytherapy, planned in accordance to GEC ESTRO dosimetric guidance or SBRT delivered to 36.25Gy in 5 fractions to the PTV. All participants will receive Barrigel, a rectal spacer, aiming for 1cm separation between the prostate and anterior rectal wall. The primary endpoint is the minimally

important difference on the validated EPIC 26 questionnaire. Secondary endpoints include further validated patient reported outcomes, CT CAE scoring and survival outcomes.

The trial received HRA and HCRW approval and is now open for recruitment at the Royal Surrey Hospital with patients successfully enrolled. Multi-centre approval has been granted, with additional UK and European centres invited to participate.

Conclusion

The LDR BURST trial is the world's first study to directly compare the toxicities of LDR brachytherapy and SBRT with a rectal spacer gel. It will provide essential toxicity data to help educate clinicians and more importantly patients when choosing between these radical treatment options. Given SBRT's growing role as an accessible treatment, delivered in a handful of sessions, the data will be instrumental in defining its place alongside LDR brachytherapy.