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a retrospective clinical study of treatment outcomes will be performed, with all study participants receiving virtual hdrb±ebrt. the study will be conducted in multiple participating centres across australia, new zealand and the united kingdom. study participants will comprise a highly selected group of patients who have failed local and/or systemic treatment, and who would otherwise not qualify for entry into ninja. the selection of patients will be guided by a set of selection criteria, which will be prospectively validated. all patients will be followed for the primary endpoint of overall survival, with a planned follow-up of up to 5 years following trial entry. patients will be offered up to two courses of trial treatment, but will not be re-treated following trial completion. if patients are not suitable for initial trial treatment, they will be offered trial treatment at a later date. for t1 and t2 patients, there are no clear data to support the concept of intra-fraction imaging. this is largely because common ablative techniques that can be used to produce lesions with large margins involve very high doses and several such approaches require the patient to be in the supine position. sub-minute dose delivery using very high energy electron beams is therefore difficult to implement. the data suggest that a minimum dose is given to sufficient levels of the tumour volume and to the primary lymphatics to achieve local control. the data are inconsistent in demonstrating the benefit of full dose delivery to peripheral nerves versus primary resection margins. the conventional approach to rectal cancer also involves full dose delivery, and the data suggest that dose escalation to the primary site is clinically equivalent to the conventional technique.



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there is no robust evidence to support the use of 3d planning and/or treatment verification. common 3d imaging techniques such as kv and mv imaging are susceptible to changes in treatment positioning. the use of validated dose distribution maps such as γ -index and isodose-surface maps is a useful measure of accuracy. these require more effort to generate, and have less clinical utility. this is because they do not measure specific metrics of dose delivery, such as homogeneity, and therefore have limited clinical utility. the trial has approval from the australia new zealand aids council, the university of western australia ethics committee, the london - brighton & sussex research ethics committee b, and the monash university human research ethics committee. hrra has also recently obtained approvals from relevant national ethics committees in the united kingdom, france, and belgium. concurrent with recruitment of patients to the trial, the study will be undertaken to establish a solid patient experience to inform the experimental treatment approach. recruitment will be driven by a range of means, including advertisements on social media, and on relevant organisations websites. a patient recruitment database will be used to identify potential trial candidates, and a trial information package will be designed to provide all necessary information to interested patients. the package will be stored on the hrra trial website, and any patients interested will be invited to complete an electronic screening questionnaire. 5ec8ef588b

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