Title:
Update on the ELECTRA trial: Intraoperative Electron Radiotherapy in Rectal Cancer – a feasibility trial

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Background:
In the management of rectal cancer, treatment of locally advanced (LARC) or locally recurrent (LRRC) rectal cancer poses some of the greatest therapeutic challenges. LARC affects 10-15% of patients and LRRC can affect up to a further 12%, amounting to approximately 4,000 patients in the UK each year. Both LARC and LRRC can cause severe symptoms and impair quality of life significantly. Surgery remains the best option for cure in patients with LARC and LRRC, provided that the tumour can be completely removed. Completeness of excision has been identified as one of the key outcome measures that determines prognosis after surgery for LARC and LRRC, with incomplete removal associated with disease recurrence.

Intraoperative Electron Radiotherapy (IOERT) represents a promising additional treatment modality that may improve outcomes in the treatment of LARC and LRRC, where high-energy electron beam irradiation is applied directly to the tumour bed during extended margin surgery. In this setting, the aim of IOERT is to help mitigate against microscopically positive resection margins in the most challenging cases of LARC and LRRC. To date, however, there have been no randomised blinded studies to assess the effectiveness of IOERT in LARC and LRRC.

Trial design:
ELECTRA is a blinded, randomised feasibility study. Participants are randomised 1:1:1 to extended margin surgery plus either: no IOERT, standard dose IOERT (10Gy) or high dose IOERT (15Gy). The study is primarily designed to assess the feasibility of recruiting participants, delivering randomised treatment, blinding treating clinicians and participants, and collecting study endpoints. Participants with LARC or LRRC involving the pelvic sidewall or posterior pelvis compartment, and with predicted narrow or close surgical margins, are recruited at the commencement of their treatment pathway and prior to neoadjuvant therapy. They are followed for a minimum of 12 months following randomisation. Primary endpoints include number and percentage of participants who accept randomisation, receive the allocated treatment, remain blinded in follow-up, and provide clinical and questionnaire outcome data. Here we present the progress of the trial and examples of cases treated.

Clinical trial identification
ISRCTN reference: ISRCTN48105173