PE31 NeuroSAFE RALP vs standard RALP for men with localized prostate cancer (NeuroSAFE PROOF): update on an RCT in progress

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Introduction & Objectives: Potency and urinary continence are improved when the neurovascular bundles are spared during a nerve-sparing (NS) robot-assisted radical prostatectomy (RALP). Often NS is not performed when there is concern of positive surgical margins from extra-capsular extension of the prostate tumour. However, this can unnecessarily compromise functional recovery from RALP when the prostate cancer is, in fact, organ-confined. The NeuroSAFE technique involves intra-operative frozen section analysis of the postero-lateral aspect of the prostate margin during RALP with a view to safely navigating NS RALP. The NeuroSAFE PROOF trial (NCT03317990) is the first RCT to compare NeuroSAFE RALP vs. standard of care RALP.

Materials & Methods: NeuroSAFE PROOF is a prospective, multi-centre, single-blinded, phase 3 trial randomising patients 1:1 to NeuroSAFE RALP (intervention) or standard RALP (control). Men with localized prostate cancer, no history of previous treatment, and IIEF-5 score >21 are eligible for inclusion. We have completed recruitment to our initial feasibility study of 50 patients. The primary outcome is erectile function (EF) recovery at 12 months assessed by objective, validated, patient reported questionnaires. Oncological safety (biochemical failure, biochemical recurrence and adjuvant treatments) will be continuously monitored by the data monitoring committee. Remote follow-up for functional and oncological outcomes is planned for five years following treatment. Preliminary power calculations estimate a necessary sample size of 276 participants to demonstrate a statistically significant difference in EF recovery of 20% between intervention and control arm. Secondary outcomes will include comprehensive operative parameters, rates of NS, pathological parameters including PSM and patient reported functional outcomes; sexual satisfaction, continence and quality of life.

Results: NeuroSAFE PROOF has ethical approval (REC reference 17/LO/1978). NeuroSAFE PROOF is supported NIHR Research for Patient Benefit funding (NIHR reference PB-PG-1216-20013) and the Jon Moulton Charitable Foundation (UK charity no. 1109891). At the time of writing we have recruited and randomised 85 patients at four participating sites in the UK.

Conclusions: NeuroSAFE PROOF will provide much needed level 1 evidence about the NeuroSAFE technique. This trial represents ‘evaluation’ stage as per the IDEAL recommendations for the introduction of complex innovations in surgical practice. Given the limited availability of the NeuroSAFE technique in the UK NHS healthcare setting presently, this trial represents a unique opportunity to perform this randomised controlled trial. We report this abstract as a Trial in Progress.