Protocol for a Feasibility Study of a Cohort Embedded Randomised Controlled Trial comparing NEphron Sparing Treatment (NEST) for Small Renal Masses

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INTRODUCTION & OBJECTIVES

Historical interventional trial recruitment difficulties demand novel study conduct approaches.

We aim to assess if a novel trial design, the cohort embedded randomized controlled trial (RCT), will enable carrying out a comparison between nephron sparing treatment for small renal masses.

METHODS

Single centre prospective cohort study with an open label embedded interventional RCT comparing percutaneous cryoablation (intervention arm) to partial nephrectomy (PN; control arm).

The trial incorporates qualitative research techniques to assess barriers and recruitment improvement opportunities.

Eligibility for RCT Biopsy proven single renal cell carcinoma lesion, Charlson comorbidity index<3, Performance status 0 or 1, Equal technical feasibility for PN and percutaneous cryoablation.

Primary outcome Participant recruitment.

Secondary outcomes Participant trial retention, health-related quality of life, treatment complications, blood transfusion rate, Intensive Care Unit admission and renal replacement requirement rates, length of hospital stay, time to return to pre-treatment activities, number of work days lost, and health technologies costs.

Ethics UK HRA REC 19/EM/0004

Trial registration ISRCTN18156881

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