

Knee Fix or Replace Trial (KFORT): A Randomized Controlled Feasibility Study

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Purpose: Distal femoral fractures (DFFs) in the elderly, osteoporotic population present a significant treatment challenge. The primary objective of this study was to assess the feasibility of conducting a full-scale, appropriately powered randomized controlled trial between internal fracture fixation (IFF) and distal femoral replacement (DFR) for DFFs in this specific patient population.

Methods: A total of 7 centers recruited patients to the study. Inclusion criteria included patients aged over 65 years with a DFF and the treating surgeon felt they were suitable for either IFF or DFR. The primary clinical outcome measure was EuroQol-5 Dimensions (EQ-5D) at 6 months following injury and secondary clinical outcome measures included Oxford Knee Score (OKS) and Disability Rating Index (DRI). Feasibility outcome measures included patients' willingness to participate, clinicians' ability to recruit, dropout rates, ability to capture data, estimates of standard deviation to inform the sample size calculation, and the main cost-drivers. Other outcome measures included surgical time, transfusion requirement, complications, mobility status on discharge, and length of hospital stay.

Results: Between October 2015 and August 2017, 36 patients met the inclusion criteria. Of these, 5 declined to participate and 8 were not recruited, leaving 23-patients to randomize. During the follow-up period 5 of 23 patients (22%) withdrew from the trial and 6 patients (26%) died. At 6 months, the EQ-5D utility index was lower in the DFR group. Mean inpatient costs were around £6,500 more in the DFR group. For a powered trial, a total sample size of 1400 would be required, hence requiring 234 centers, recruiting over 3 years.

Conclusion: This study has found running a full-scale trial not feasible, based on the numbers required to power it. Also, based on this feasibility trial we cannot make any recommendations as to the best treatment modality for DFF in the elderly population.