Retrograde intramedullary nail fixation compared with fixed-angle plate fixation for fracture of the distal femur: the TrAFFix feasibility RCT

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Plain English summary

Breaks of the lower end of the thigh bone are increasingly common injuries. Two operations are used to treat these injuries: a rod placed along the centre of the bone or a plate attached to the edge of the bone. It is not clear which is better. We report the results from a study that will help develop the design of a definitive study to test which operation produces the best outcomes for patients.

Adult patients with a break at the end of the thigh bone treated in one of seven hospitals were eligible to take part in the study. Participants were treated with one of two operations; the choice was made by chance using a computer program. Participants’ basic information and pre-injury health status were recorded and participants were followed up at 6 and 16 weeks.

We assessed the rate at which participants agreed to take part in the study and the number who completed follow-up. A value-for-money analysis was performed to determine how to plan this element of a future study. Staff and patients were interviewed about the study processes and the context of the treatments and hospitals to understand how the treatments work and the practicalities of delivering the study.

Lower than expected numbers of participants took part in the study; 173 patients were considered for the study, but only 23 agreed to participate. The main reason was that several of the participating surgeons felt strongly that one or the other operation was superior. The rate of follow-up was similar to that of other studies using these treatments.

Therefore, the proposed definitive trial is unlikely to be successful if designed in the same way as this feasibility study. Several important considerations that informed the planning of this study were found not to hold true. We believe a modified study could be delivered and could answer this important research question.
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This report
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