HipHOP

IRAS ID: 271885

ISRCTN ID: 11097021

HipHOP Study

Feasibility study for a comparative trial of hybrid or cemented implants for total hip replacement.

Hip arthroplasty with Hybrid Or cemented implants: Patient reported outcomes

Scientific summary of results:

In the UK, over 90,000 Total Hip Replacements (THR) are performed annually. Studies have shown that 10-30% patients do not achieve optimal function outcomes. High quality RCTs to investigate this deficit in function are lacking. Furthermore, research to identify factors that determine patients' outcome after THA has been identified as a James Lind Alliance priority.

We designed this pragmatic study to evaluate the feasibility of a RCT comparing patient-reported functional outcomes after hybrid vs fully cemented THR(ISRCTN11097021). Both quantitative and qualitative work was planned.

Objectives of workstream 1 were to assess the acceptability of randomisation to participants and surgeons; monitor intra- and post- operative safety; collect data to inform a sample size calculation, collection Patient Reported Outcome Measures(PROMs) and assess the feasibility of conducting a within-trial cost-utility analysis.

Workstream 2 took the form of qualitative interviews to understand patient experiences of the trial and their reasons for taking part or not; understand surgeons' perceptions of the trial, factors affecting willingness to participate, and barriers to implementation of trial findings; explore experiences of healthcare professionals involved in the research (HCPs) to inform procedures for the definitive RCT.

The PPI group collaborated on the trial design and co-produced patient facing documentation. Patients were approached in pre-operative clinic and consenting patients were randomised to a hybrid or cemented replacement. Participants completed questionnaires at baseline and at 6 weeks and 3-6

This study is funded by the National Institute for Health Research (NIHR) Research for Patient Benefit Programme (Grant reference PB-PG-0817-20012).
The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

months post-operative; clinical data were collected after surgery. Qualitative interviews were conducted with participants, non-participants, surgeons and HCPs.

The target of 40 patients were successfully recruited from 2 sites within the target time frame. The ratio of successful recruitment to eligible patients was 0.61 across both sites. Estimation of clinical data enables an accurate sample size estimate for a future Phase III study accounting for possible site/surgeon effects. A total of approximately 400 patients will be required to obtain a sufficiently powered study.

Treatment crossovers occurred in 4 patients, all related to bone quality. Four patients were withdrawn due to not undergoing surgery within the study window as a result of the pandemic.

Trial follow-up was 100%. Patient Reported Outcome Measures were successfully completed by all patients at all time points.

Indicative economic analysis suggests that hybrid implants are cost-effective in comparison to cemented ones.

Patient and HCPs generally found the trial acceptable and workable. Some patients were wary of randomisation, but both implants being routine treatments with good track records seemed reassuring. Some declined participation because they did not want treatment allocated at random, or because blinding was off-putting. Surgeons' perceptions of equipoise varied, and some surgeons declined participation because they were skilled in only one implant procedure.

Our study results have yet to be presented or published. However, we can conclude that a full trial will be both feasible and practicable. Following detailed trial planning based on our results we aim to submit a bid to HTA for funding to run the full trial.