Cemented Versus Cementless Unicompartmental Knee Arthroplasty (UKA) - A Single-blind Randomised Controlled Trial

Clinicaltrials.gov ID: NCT05935878

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Original Study Design (Protocol)

Design: Prospective, randomised

Size:40 subjects in total will be recruited. 20 in each arm. A power calculation determined that a minimum of 16 patients were required in each arm to detect a clinically significant difference in migration (0.2 mm).

Methods: Patients will be recruited from the routine waiting list at the Nuffield Orthopaedic Centre. All subjects will have the procedure explained and will be fully consented prior to the procedure. Patients will be excluded from the study if they have significant systemic illness (ASA-3 or more) or if their size makes X-ray analysis impossible.

Randomisation: Patients will be randomly allocated to receive either an uncemented or cemented Oxford UKA. This will be performed using a randomisation program based on optimisation (Minim®). Subjects will be stratified according to sex and age (<55, >55).

Operation: All subjects will undergo the same surgical approach. 0.8 mm tantalum marker balls will be placed at standardised sites on the femur and tibia in all cases. All cemented components will be secured using the same cement. Cementless components have a hydroxyl-appatite coating to facilitate bone ingrowth.

Follow-up: All patients will be followed up at 0, 3, 6, 12 and 24 months with clinical and radiological assessment. Clinical assessment will involve documentation with patient based validated knee scores ie Oxford Knee Assessment Score and non-validated but widely used surgeon based American Knee Society Score and Hospital for Special Surgery Score. Patients will undergo RSA examination and fluoroscopy at 6, 12 and 24 months post surgery to study implant migration and occurrence of radiolucency.

* In September 2009, ethical approval was received Oxfordshire Research Ethics Committee B to extend patient follow-up to 60 and 120 months.