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*Cu*rved versus *S*traight Stem Uncemented *T*otal Hip Arthroplasty *O*steoarthritis *M*ulticenter trial (CUSTOM): design of a prospective blinded randomised controlled multicentre trial

Loes W A H van Beers,[1] Jakob van Oldenrijk,[2] Vanessa A B Scholtes,[1] Carel H Geerdink,[3] Bob B A M Niers,[3] Wouter Runne,[1] Mohit Bhandari,[4] Rudolf W Poolman[1]

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For numbered affiliations see end of article.

Correspondence to
Loes W A H van Beers;
l.w.a.h.vanbeers@olvg.nl

ABSTRACT

Introduction: Answering the demands of an increasingly young and active patient population, recent developments in total hip arthroplasty (THA) have shifted towards minimising tissue damage. The Collum Femoris Preserving (CFP) stem was developed to preserve the trochanteric region of the femur, which potentially preserves the insertion of the gluteus musculature. This might accelerate early postoperative rehabilitation and improve functional outcome. Currently the functional results of the CFP stem have not been compared with conventional straight stems in a randomised controlled trial (RCT). The primary purpose of this trial is to compare the functional result of CFP stem THA with conventional uncemented straight stem THA, measured by the Dutch Hip disability and Osteoarthritis Outcome Score (HOOS) at 3-month follow-up.

Methods: A prospective blinded multicentre RCT will be performed. We aim to recruit 150 patients. The patients will be randomly allocated to a THA with a straight or a curved stem. All patients, research assistants, clinical assessors and investigators will be blinded for the type of prosthesis for 5 years. Clinical assessments and roentgenograms will be taken preoperative, at 6 weeks after surgery, at 1, 2, 3, 4 and 5 years after surgery. Patient reported outcome measures (PROMs) will be obtained at the same follow-up moments. In addition, the PROMs will also be sent to the patients at 3 and 6 months after surgery. The HOOS at 3-month follow-up will be our primary outcome.

Ethics and dissemination: This trial will be performed in accordance with the Declaration of Helsinki. A local ethics committee has approved this trial. Written informed consent will be obtained from all participating patients. All serious adverse events will be reported to the ethics committee.

Results: Results will be submitted for publication to an orthopaedics related journal.

Trial registration number: NTR1560.

Strengths and limitations of this study

- A good methodological quality, which reduces the risk of bias.
- A multicentre randomised controlled trial.
- Maximally blinded (patients, clinical assessors, investigators and data analysts are blinded for the type of implant).
- A research assistant is hired for this study, to ensure that there will be complete data and a maximal follow-up.
- Sealed envelopes instead of a digital system are used for the randomisation.

INTRODUCTION

For years, developments in total hip arthroplasty (THA) have focused mainly on improving implant survival, resulting in long-term survival rates of more than 90% for uncemented as well as cemented stems.[1]

There is a recent increase in uncemented hip replacements, especially in young and more active patients. Uncemented stems are currently the preferred implant of choice for these patients, providing that there is a good bone quality.[2] The Zweymuller stem is a commonly used uncemented straight stem and studies have shown excellent 10-year survival rates of 90–100%.[3–6] Weissinger *et al*[7] have shown a reoperation rate of 6.8% after 20 years. Furthermore, stability of the implant was not affected by any proximal osteolysis.[8 9] The proximal anchorage of this stem requires the use of a box chisel cutting a slot in the trochanteric fossa near the insertion of both the gluteus medius and the piriformis tendon to obtain entry in neutral

alignment. A previous cadaver study by van Oldenrijk *et al*[10] demonstrated a median gluteus medius midsubstance surface area damage of 22% (minimum 6, maximum 40%) after Zweymuller stem placement using a lateral transgluteus approach. Moreover, the external rotators were found to be unintentionally transected in one of five hips using this approach. Damage to the insertion of the gluteus musculature is an important cause of postoperative pain at the greater trochanter and reduced abductor strength, resulting in limping and a positive Trendelenburg gait.[11–13]

In the young and active patient population, recent developments have, therefore, shifted towards minimising tissue damage, thereby retaining normal bone physiology without compromising implant stability. This resulted in the modification of surgical techniques and the development of innovative bone and soft tissue-preserving implants, such as short stem hip arthroplasty. The aim of these developments was to accelerate early postoperative rehabilitation, improve functional outcome and preserve bone stock for future revisions.[14]

Short stem THA aims to combine well-established anchoring principles with bone preservation. Pipino and Calderale [15] introduced the Biodynamic stem. This stem preserves the collum femoris, thereby preserving proximal bone stock for any future revisions. Furthermore, it preserves the trochanteric region of the femur. As such, it preserves the gluteal insertions on the greater trochanter, which may be beneficial as compared to a conventional stem, as this may potentially accelerate early postoperative rehabilitation. The Biodynamic stem, showing good medium and long-term survival rates,[16 17] was later modified into the collum femoris preserving (CFP) stem (Waldemar Link, Germany). A case series (mean follow-up of 5.1 years) demonstrated excellent integration and survivorship at medium follow-up (mean 5.1 years), with a revision rate of 0.21 per year.[18–28] Clinical follow-up also showed good functional recovery and DEXA analysis of 10 patients showed minimal periprosthetic bone loss.[16 18] Two-year follow-up migration assessment using radiostereometry showed low migration, suggesting a favourable long-term outcome.[26 29] The quality of this currently available evidence is low, and no study has compared this stem with a conventional stem, so only a weak recommendation can be provided for clinical usage of these short stem designs.[30] Stronger evidence is necessary, preferably prospective multicentre randomised trials, before widespread use can be recommended.[30]

Since the potential benefits of the CFP stem have not yet been compared with conventional straight stems in a randomised controlled trial (RCT), the potential additional benefit in terms of short-term rehabilitation remain to be determined. We aim to compare the early (3 month) and medium (up to 5 years) term functional result of a CFP stem THA to conventional straight stem THA. The primary purpose of this trial is to compare the functional result of CFP stem THA with conventional uncemented straight stem THA, measured by the Dutch version of the Hip disability and Osteoarthritis Outcome Score (HOOS)[31] at 3-month follow-up.

The secondary objective will be an evaluation of secondary outcomes discussed in detail below. Since the CFP stem may require less dissection of the gluteal musculature off the greater trochanter, we expect to find a better short-term functional result after CFP stem THA compared with conventional straight stem THA, as reflected in higher HOOS.

METHODS

Trial design

A prospective blinded randomised controlled multicentre trial with parallel groups will be performed at Onze Lieve Vrouwe Gasthuis (OLVG) in Amsterdam and at Ikazia hospital in Rotterdam, both in The Netherlands. A total of 100 patients from OLVG and 50 patients from Ikazia will be recruited. Three orthopaedic surgeons from OLVG, and two orthopaedic surgeons from Ikazia, participate in this trial. The allocation ratio between the two interventions will be 1:1, and a superiority design will be used. This trial is registered at the Dutch Trial Registry (Nederlands Trial Register, http://www.trialregister.nl) on 25 November 2008, file number NTR1560.

Participants

We will include patients between 18 and 70 years with osteoarthritis of the hip, who are not responding to conservative therapy, who meet the clinical criteria to undergo a cementless THA, and are willing to sign written informed consent. Consecutive patients from the waiting list for a total hip replacement will be approached for participating in this trial if they meet the inclusion criteria. Patients will be excluded when they: are not able to fill out the Dutch questionnaires; have morbid obesity with a body mass index of more than 40 mm Hg; have an altered anatomy resulting in impossibility for one of the procedures; have a life expectancy of <5 years; have had a lower extremity amputation; have a known alcohol or drugs abuse; have an active malignant disease or current cytostatic treatment; are participating in another clinical trial; have contralateral hip pain; have had a previous hip arthroplasty (ipsilateral or contralateral), or when they have avascular head necrosis due to sickle cell anaemia.

All orthopaedic surgeons will be informed about this trial through presentations, posters and newsletters. The orthopaedic surgeons will screen all patients in the outpatient clinic for eligibility, and they will inform eligible patients about the trial. A researcher will contact the patient by phone to resolve any questions. When the patient agrees to participate in this trial, informed consent has to be signed by both the orthopaedic surgeon or research assistant and the patient. After enrolment in this trial, patients will be assigned to a

study identification number. Only the study identification number will be used on data forms and in the databases. The encryption between the study identification number and the personal information will only be accessible for the research coordinator of this trial.

Randomisation and blinding

After signing the informed consent, the patient will be randomly allocated to THA with a straight stem or a curved stem. Stratified block randomisation will be used as allocation method. Blocks consist of 10 consecutive surgical procedures. At the end of each block an equal distribution of patients between the two groups will have been reached. Patient allocation will be stratified to surgeon, resulting in an equal distribution of surgical expertise and technique variation in each group. Randomisation will not be performed until the moment of surgery. The surgeon will, therefore, perform preoperative templating for both stems, and both stems and their instrumentation trays will be available in the surgery room. Since a digital randomisation system proved to be unsuccessful in our hospital due to technical difficulties, randomisation will be performed using envelopes. We will use randomisation envelopes that are sealed, sequentially numbered, opaque and blinded. An independent investigator will make these randomisation envelopes available to the surgeon in the operating room, after the patient is under anaesthesia, and just before incision. Both types of implants are ready to use in the operating room. All patients, researchers, clinical assessors and investigators will be blinded for the type of prosthesis for the total duration of the follow-up: 5 years. A pop-up message will be attached to the patient records in the electronically maintained hospital information system. This pop-up message is a reminder that the patient and clinical assessors are blinded, and therefore, the roentgenograms should not be shown. Only the orthopaedic surgeon will verify the roentgenograms, so in case there are any problems, they can be intervened. Data will be processed and analysed by blinded investigators. After finalising data analyses the blinding will be broken for publication purposes.

The number of deblinded patients will be recorded and presented in final reports.

Interventions

All participating surgeons should have gained experience with both implants. At least five procedures for both implants should have been performed prior to participating in the trial. The learning curve for the CFP stem is assessed in an earlier study,[28 32] and an acceptable level of proficiency is assumed after performing five procedures.

A lateral transgluteal approach in lateral decubitus position is used in all patients.

The same rehabilitation protocol will be used for both groups. Postoperatively, patients are allowed to fully weight bear with the use of crutches from the first postoperative day, continuing crutches if necessary during the first 6 weeks.

Straight stemmed THA

Patients randomised into the straight stem group will undergo surgery for THA where a straight, cementless, Alloclassic stem (Zimmer, Warsaw, Indiana, USA) will be used. This stem is inserted parallel to the longitudinal axis of the femur.

Curved stemmed THA

Patients randomised into the curved stem group will undergo surgery for THA where a curved, cementless, CFP stem (Waldemar Link, Hamburg, Germany) will be used. This stem follows the curvature of the remaining femoral neck. Two curvatures are available: A for coxa valga and norma, and B for coxa vara. The curvature will be assessed preoperatively by templating the hip.

Cup

A Trabeculae Oriented Pattern (TOP) cementless hemispheric cup (Waldemar Link, Hamburg, Germany) with a polyethylene liner will be used in both groups. The TOP cup has a biequatorial dissociation with a medial-caudal recess to allow a wider range of motion and an elevated cranial rim to reduce the risk of dislocation.[17] A follow-up study of 301 TOP cups showed no detachment, migration or osteolysis after 7 years.[18] All implants are positioned without the use of navigation.

Head

In both groups a 32 or 28 mm ceramic head is used.

Outcome measures

Primary outcome

The Dutch version of HOOS[31] at 3 months postoperative, will be our primary outcome. The HOOS is a patient-reported outcome measure (PROM) that consists of five subscales; pain, other symptoms, function in daily living, function in sport and recreation and hip-related quality of life. Standardised answering options are given for each question (five Likert boxes) ranging from 0 to 4. A normalised score (100 indicating no symptoms and 0 indicating extreme symptoms) is calculated for each subscale.

Secondary outcomes

Secondary outcomes will be the amount of reoperations due to implant-related complications, for example, bleeding or vascular damage, neurogenic damage, fractures, dislocation, infection, loosening, deep venous thrombosis. Other secondary outcomes are pain in the ipsilateral and contralateral hip, knees and back, measured by a numeric rating scale (NRS), abductor strength measured by the Trendelenburg test,[33] walking ability measured by the Timed Up and Go (TUG) test,[34 35] physical functioning measured by the Harris Hip Score (HHS),[36] general health measured by the

Short-Form 12 item (SF-12) questionnaire,[37] quality of life by the EuroQol 5 Dimension (EQ-5D) questionnaire,[38] and position of the prosthesis. The position of the prosthesis will be measured on weight-bearing anteroposterior pelvis with the patient's feet facing forward and hip faux profile roentgenograms. Preoperatively an X-ray will be taken which includes a ball of known diameter to enable calibration. Postoperatively X-rays are taken at day 1, 6 weeks, and annually up to 5 years after surgery. An assessor who is not involved with the surgical procedures will perform all measurements.

The clinical assessments, containing the range of motion of the hip, the Trendelenburg test, the TUG test, measuring leg length discrepancy and asking for the occurrence of any complications, will be performed at baseline (within 1 week prior to surgery), at 6 weeks after surgery, at 1, 2, 3, 4 and 5 years after surgery. A trained researcher will perform all clinical tests. Roentgenograms will be taken at the same time points.

The PROMs, containing the HOOS, NRS, HHS, SF-12 and EQ-5D, can be filled out using either pen and paper or web-based forms. The PROMs will be sent to the patient's home address (including prestamped return envelopes) or e-mail address. Patients are asked to fill out the PROMs at the same follow-up moments as the clinical assessments. In addition, the PROMs will also be sent to the patients 3 and 6 months after surgery. All follow-up moments are presented schematically in table 1. Every patient will receive a reminding card containing the date of surgery and the subsequent months/years of clinical follow-up. For every follow-up visit, patients will be contacted by phone to make an appointment. Patients who have not responded to the PROMs, are contacted by phone as a reminder. Patients will be kept informed about the trial by sending them newsletters, approximately twice a year. In addition, every patient chart has a note for doctors, that in case of any complication the research coordinator should be contacted.

Sample size

Sample size calculation is based on the HOOS pain subscale, to detect a difference between the two groups at 3 months postoperative. De Groot *et al*[31] found a mean HOOS pain score of 65.4 points with an SD of 14.3 in patients 9.5 months after THA. We consider a 10% difference in outcome clinically relevant, resulting in a seven-point difference.[39] Based on these assumptions, setting α at 0.05 and the power level at 80%, a sample size of 67 patients in each group is required to detect a statistically significant difference.

We expect a maximum drop-out rate of 10%, resulting in a total of 150 patients (75 patients in the curved stem group and 75 patients in the straight stem group).

We expect to recruit the 150 patients within a period of 2 years.

Statistical analyses

To investigate the effect of both implants, we will use generalised estimating equations (GEE) for longitudinal analysis in SPSS. All patients who withdraw from the trial after surgery, and patients who undergo a revision surgery, will be included in an intention-to-treat analysis. Both intention-to-treat analysis and per-protocol analysis will be performed. This method takes into account the dependency of observations within a patient, and the fact that not all patients may be assessed at each time point (missing data).

Primary analyses

In the primary GEE model, the outcome variable studied (eg, physical function on the HOOS) will be analysed as a dependent variable, using implant allocation (1, CFP; 0, Zweymuller) and time as key independent variables. The primary endpoint of the study is on the effect at 3 months, but all time moments will be analysed in the same GEE model.

Secondary analyses

In the secondary GEE model, the outcome variables studied (eg, physical function on the HHS, general health on the SF12, quality of life on the EQ5D, walking ability on the TUG, pain on the NRS, hip range of motion, abductor strength on the Trendelenburg test, position of the prosthesis and leg length discrepancy on the roentgenograms, satisfaction) will be analysed in a similar way. To evaluate whether the two implant groups differed in change over time, the interaction term of group and time (group×time) will be assessed. Time will be included as a dummy variable (reference=baseline T0), and seven interaction terms will be analysed (T1 6 weeks×group, T2 3 months×group; T3 6 months×group; T4 1 year×group, T5 2 years×group, T6 3 years×group,

Table 1 Follow-up moments

	Preoperative	Postoperative							
	Baseline	6 Weeks	3 Months	6 Months	1 Year	2 Years	3 Years	4 Years	5 Years
PROMs	X	X	X	X	X	X	X	X	X
Clinical tests	X	X			X	X	X	X	X
Roentgenograms	X	X			X	X	X	X	X

PROMs, patient-reported outcome measures.

T7 4 years×group, T8 5 years×group). All models will be corrected for centre of inclusion and surgeon. In additional analysis, we will investigate the possible confounding effect (defined as more than 10% change in the parameter estimate for group×time) of several variables (body mass index, gender, ASA-classification, comorbidity, mental health, other joint pain). At the following time points following the surgery (T4, T5, T6, T7 and T8), we will describe the incidence of reoperations (both implant groups) using descriptives. For all analysis, a two-tailed value of $p<0.05$ is considered to be significant.

Data storage

Data will be entered into a digital database (SPSS), and after the data entry, paper data collection forms will be stored in an archive. Both paper forms and digital databases will be accessible only to the research coordinator.

Steering and data monitoring committee

No official steering committee has been appointed for this study. The following representatives from the participating organisations are involved in the project oversight and control: RWP (principal investigator and sponsor), JvO, CHG, BBAMN, VABS and LWAHvB. All study-related problems or (serious) adverse events will be discussed with the principal investigator RWP, and researchers VABS, LWAHvB and JvO. SAEs will be officially reported to the ethical committee. The ethical committee judges whether the safety of the patients is jeopardised, and whether the trial can be continued or not.

There is no official data monitoring committee. Data entry will be performed by one of the researchers (LWAHvB). All entered data will be checked and cleaned (LWAHvB and VABS) according to the quality handbook of the emgo+institute for health and care research (http://www.emgo.nl/kc). In addition, a random sample of 20% of the data will be re-entered by another researcher (JvO) to check for inconsistencies. A third researcher (VABS) will be involved with the data processing and analysis, which will be performed without knowledge of the allocation key. All data analysis (VABS) will be discussed with the researchers (RWP, JvO and LWAHvB) prior to deblinding, before final presentation of the results.

Interim analysis will be performed after 2 years. Data analysts and researchers are still blinded to the type of prosthesis at that time point. Results of the interim analysis will be discussed with the researchers.

Ethics and dissemination

This trial will be performed in accordance with the Declaration of Helsinki. All substantial amendments to the protocol will be notified to the ethics committee and to the competent authority. Non-substantial amendments will not be notified to the accredited METC and the competent authority, but will be recorded and filed by the sponsor. Written informed consent will be obtained from all participating patients. The research coordinator will report all serious adverse events within 24 h after noticing any, using the online submission system of the ethics committee. The ethical committee judges whether the safety of the patients is jeopardised, and whether the trial can be continued or not. Results will be submitted for publication to an orthopaedics-related journal.

Protecting against sources of bias

Selection bias

In this trial, the risk of selection bias is reduced by approaching all consecutive eligible patients.

Furthermore, randomisation will not be performed until the moment of surgery. This will prevent selecting patients for a specific type of prosthesis.

Performance bias (blinding)

Unblinded patients allocated to an intervention which they do not prefer, may feel resentful. This may lead to performance bias.[40 41] In this trial, all patients will be blinded to the type of prosthesis, reducing the risk of performance bias.

Performance bias (surgeon expertise)

Requiring a minimum number of procedures prior to initiating the trial reduces the risk of performance bias.

Detection bias

The clinical assessors who will perform the clinical tests will be blinded, to reduce the risk of detection bias.

Attrition bias

To reduce attrition bias, a blinded research assistant is the direct contact person for all trial patients. Efforts are undertaken to minimise the amount of patient drop-out or lost to follow-up. Moreover, all PROMs and clinical assessment data is verified to prevent incomplete data.

Publication bias

By publishing this protocol, we would like to prevent publication bias. Results of this trial will be submitted for publication in a peer-reviewed journal.

Minimising cointerventions and contamination

Crossover between intervention groups can occur, for instance, when a revision surgery will be performed and another type of stem will be implanted. All patients will be analysed in the group to which they were allocated following the intention-to-treat analysis. Additionally, we can perform per-protocol analysis.

DISCUSSION

Authors of surgical RCTs often fail to report measures to prevent bias.[42–46] Several reviews of RCTs in orthopaedic surgery have studied the reporting of bias prevention. They found that this is often not well reported. Blinding

of outcome assessors, concealment of allocation, and intention-to-treat analysis are types of bias preventions that are often not reported.[40 41 47] In this trial, extensive measures will be taken to reduce the risk of bias. It will be a challenge to keep all involved persons, patients as well as research staff, blinded for 5 years. These strenuous measures to reduce the risk of bias may serve as a model for future implant-related orthopaedic RCTs. This trial will be the first RCT that compares the early and medium-term functional results of the CFP stem THA with conventional straight stem (Zweymuller) THA. Herewith, this trial can contribute to the clinical evidence around short stem THA.

At first sight, 3 months follow-up might not be the most clinically relevant time point to evaluate. This time point was chosen as it best reflects the timing to evaluate the theoretical advantage of the CFP stem as compared with the Zweymuller stem; for example, that the gluteal musculature might be less damaged. This preserving of gluteal musculature might be beneficial for the acceleration of rehabilitation/improved physical functioning of the patients, in particular, in the first months after surgery. The intention of this trial is to evaluate whether the theoretical advantages of the CFP stem do really result in better physical functioning, compared to the Zweymuller. For that reason, we choose 3-month follow-up as our primary end point. Naturally, mid-term and long-term results of prosthetic stems are valuable. For that reason, we will follow all patients up to 5 years after surgery.

Author affiliations
[1]Department of Orthopaedic Surgery, Joint Research, Onze Lieve Vrouwe Gasthuis (OLVG), Amsterdam, The Netherlands
[2]Department of Orthopaedic Surgery, Academic Medical Center (AMC), Amsterdam, The Netherlands
[3]Department of Orthopaedic Surgery, Ikazia Hospital, Rotterdam, The Netherlands
[4]Department of Surgery, McMaster University Hospital, Hamilton, Ontario, Canada

Contributors All authors contributed to the design of this trial protocol. LWAHvB, JvO, VABS and RWP contributed to writing the manuscript. VABS, LWAHvB and JvO contributed to the data analysis plan. All authors contributed to the manuscript and read and approved the final manuscript.

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Competing interests None declared.

Patient consent Obtained.

Ethics approval Medical Research Ethics Committees United and Verenigde Commissies Mensgebonden Onderzoek, Nieuwegein, The Netherlands approved the trial on 16 September 2008, file number NL21637.100.08.

Provenance and peer review Not commissioned; externally peer reviewed.

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Loes W A H van Beers, Jakob van Oldenrijk, Vanessa A B Scholtes, Carel H Geerdink, Bob B A M Niers, Wouter Runne, Mohit Bhandari and Rudolf W Poolman

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