

Hybrid versus poly-ethylene glenoid component in stemless anatomical shoulder arthroplasty: protocol for a multicenter, prospective, non-inferiority randomized controlled trial

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Abstract

Background

Glenoid loosening remains the most common cause of failure after anatomic total shoulder arthroplasty (aTSA). Cemented all-polyethylene glenoid components are currently considered the gold standard, but radiographic loosening remains a concern on longer-term follow-up. Hybrid glenoid components, combining cemented peripheral fixation with a porous metal central peg, may improve biological fixation and reduce radiolucency while maintaining comparable clinical outcomes. High-quality long-term comparative evidence is currently lacking. This study aims to evaluate whether a hybrid glenoid component is non-inferior to a cemented all-polyethylene glenoid component in stemless anatomic shoulder arthroplasty.

Methods

This study is a multicenter, prospective, randomized controlled non-inferiority trial conducted in three hospitals in the Netherlands. Patients will be recruited from the outpatient clinics of the participating hospitals. A total of 94 patients with primary glenohumeral osteoarthritis, an intact rotator cuff, and sufficient bone stock, who are indicated for primary anatomic total shoulder arthroplasty, will be enrolled and randomized to receive either a cemented all-polyethylene glenoid or a hybrid trabecular titanium glenoid, both in combination with a stemless humeral component. The primary outcome is shoulder function at 1 year, measured with the Constant Murley Score (CMS). Secondary outcomes include radiographic loosening, radiolucent lines, implant survival, range of motion, Oxford Shoulder Score, Subjective Shoulder Value, pain, quality of life, psychological well-being, and work-related functioning. Follow-up will take place at 6 weeks, 3 months, and 1, 2, 5, 7, and 10 years postoperatively. Analyses will be performed according to both intention-to-treat and per-protocol principles.

Discussion

This trial is designed to provide robust long-term comparative evidence on hybrid versus all-polyethylene glenoid fixation in stemless aTSA. The results will clarify whether hybrid fixation provides comparable functional outcomes and potentially improved radiographic performance, thereby supporting evidence-based implant selection in daily clinical practice.

Trial registration

This trial was retrospectively registered at ClinicalTrials.gov on April 9th 2026 with registration number NCT07520721. URL: <https://clinicaltrials.gov/study/NCT07520721?term=NCT07520721&rank=1>. At the time of registration, 26 patients had already been enrolled and recruitment was ongoing.

Background

Anatomic total shoulder arthroplasty (aTSA) has undergone considerable evolution since the first design. The field has shifted toward modular designs that better match individual anatomy.^{1,3,6,24,44} More recently, the introduction of shorter and stemless humeral components aimed to reduce complications and preserve bone.^{19,42,48,52} Although cemented fixation of the humeral component has traditionally provided reliable initial stability, concerns about the difficulty of revisions and cement-related complications have led to the development of uncemented designs.^{8,39,51} Medium to long-term data support this trend, showing excellent outcomes and low rates of loosening with modern uncemented humeral implants.^{7,39,41,43,49,51}

The glenoid side of aTSA, however, remains the weakest link. A recent systematic review with meta-analysis showed that implant loosening was the most common failure mode of aTSA with 22% of all failures caused by glenoid loosening, and 47% of all failures beyond 5 years after surgery.²⁹ Cemented all-polyethylene glenoids (PG) are the gold standard due to their track record of good clinical outcomes and high survivorship beyond 10 years.^{14,28,33,40} Still, several studies have reported high rates of radiographic changes suggestive of loosening in 30–40% of cases at 10-year follow-up.^{11,14,33}

These issues have led to the development of alternative fixation methods such as cementless metal-backed or hybrid glenoid components (HG). Early enthusiasm of metal-backed glenoid components declined due to higher revision rates in early designs.^{5,37,38,45} Although modern metal-backed glenoid components have improved and show rates of survival comparable to PG in the short term,^{27,31} there are still concerns about high levels of radiolucency and metal debris at short term follow-up.³¹ Hybrid glenoid designs have emerged as a potential compromise, theoretically combining cemented polyethylene for initial fixation with a central porous metal peg to potentially encourage long-term biological integration.

Early studies reporting short- to mid-term results suggest these designs may offer comparable clinical outcomes and complication rates to traditional cemented glenoid components, with reduced rates of radiolucent lines.^{22,32} Some retrospective studies have shown lower rates of radiolucency around the hybrid component compared to cemented all polyethylene glenoids.^{17,20} However, long-term high-quality studies are still needed to determine whether these differences translate into meaningful clinical advantages.

Therefore, the goal of this study is to evaluate the long-term outcomes of a specific hybrid glenoid design, combining cemented peripheral pegs with an uncemented porous titanium central peg, used in combination with a stemless humeral component compared to the gold standard of an all-polyethylene glenoid. The primary hypothesis of this study is that hybrid glenoid fixation is non-inferior to cemented all-polyethylene glenoid fixation regarding functional outcome. Secondary analyses will explore whether hybrid glenoid fixation is associated with more favorable radiographic outcomes, including fewer

radiolucent lines and lower rates of glenoid loosening, compared with cemented all-polyethylene glenoids, based on the theoretical advantages of hybrid fixation.

Methods

Study design

This study is designed as a randomized controlled trial to evaluate the difference in functional and radiographic outcome after operative treatment using a stemless aTSA system with either a cemented polyethylene glenoid component (PG, group 1) or a hybrid TT (Trabecular Titanium) component (HG, group 2) and identify possible risk factors that may lead to failure. The inclusion and first evaluation are performed by the orthopaedic surgeon at any of the three participating hospitals located in the Netherlands. After obtaining written informed consent, patients are randomized preoperatively to receive either a cemented all-polyethylene glenoid or a hybrid glenoid component. Both groups follow a standardized physical therapy program after the intervention. At baseline, 6 weeks, 3 months, and 1, 2, 5, 7 and 10 years postoperatively, relevant outcome data are collected through clinical evaluation performed by the treating orthopaedic surgeon or physician assistant. For an overview of events see Fig. 1. Standard radiographs of the shoulder are made at baseline, and during the above-mentioned control moments. Efforts will be made to promote participant retention, including scheduled follow-up reminders. This trial is registered at ClinicalTrials.gov (ID: NCT07520721).

Study sample

Recruitment started June 2025. At the time of manuscript submission, 26 participants had been enrolled and recruitment was ongoing. Patients requiring a primary aTSA due to symptomatic painful primary osteoarthritis with sufficient bone stock and an intact rotator cuff are selected for recruitment into the study. A patient is enrolled in the study if inclusion criteria are met and after informed consent is obtained. Subjects who do not meet the inclusion criteria or meet any exclusion criteria are excluded from the study participation. These subjects will nevertheless be registered to assess potential selection bias.

Inclusion criteria

For eligibility in this study, a subject must meet the following criteria: (I) age over 18 years of age, (II) symptomatic shoulder osteoarthritis (Samilson-Prieto grade severe) for more than 1 year and has failed nonoperative treatments; (III) indication for anatomic primary shoulder arthroplasty based on physical examination, medical history and radiologic examination, (IV) sufficient bone quality evaluated by the investigator on the basis of a risk factors analysis (presence of osteoporosis and deltoid tuberosity index measurements) and the intraoperative assessment, (V) glenoid wear morphology Walch type A1, A2 or B1,⁵⁰, (VI) glenoid retroversion less than 15°, (VII) willingness and ability to comply with rehabilitation

and complete scheduled follow-up, and (VIII) signed informed consent approved by the Ethics Committee, with all procedures conducted in accordance with the Declaration of Helsinki and its subsequent amendments.

Exclusion criteria

Patients are excluded from this study in case they meet any of the following criteria: (I) osteoporosis with a history of non-traumatic fractures, (II) steroid injections within the previous 6 months, (III) contralateral shoulder replacement within the previous 3 months, (IV) insufficient bone quality in the metaphysis (including large cysts) requiring a stemmed implant, (V) cuff repair performed during arthroplasty surgery (VI) significant proven or suspected infection of the target shoulder or any serious infectious disease, (VII) significant neurological or musculoskeletal disorders that may compromise functional recovery, (VIII) known or suspected hypersensitivity to the metal or other implant materials, (IX) any systemic disease that may affect the outcome, (X) active or metastatic neoplastic disease, (XI) chemotherapy and/or radiotherapy within the last 6 months, (XII) previous organ transplantation, and (XIII) participation in any clinical research study that may interfere with this study

Randomization and blinding

Randomization will be performed by an independent researcher not involved in patient recruitment or treatment. To reach similar distribution of the experimental and control implants among the participating sites, stratified block randomization with variable block sizes will be applied preoperatively, using the randomization tool from Research Manager (Nova Business Software, Deventer, the Netherlands). Outcome assessments will be performed by a researcher who is blinded to the type of glenoid implanted whenever feasible. The statistical analysis will be conducted by an independent analyst blinded to treatment allocation. Unblinding will only occur if required for patient safety.

Surgical technique

All procedures are performed through a deltopectoral approach using a subscapularis tenotomy. Following standard exposure, the humeral and glenoid implants are placed with the implant specific instruments provided. After the humeral bone cut, the proximal humeral bone quality will be assessed and in case of clear insufficient bone quality, the patient will receive a stemmed implant and will be considered post-randomization exclusions and handled according to the predefined statistical analysis plan. At the glenoid side, cement is used for all pegs of the polyethylene glenoid component and for the 2 peripheral pegs of the hybrid TT component.

Rehabilitation

Postoperatively, all patients will receive a shoulder immobilizer for 6 weeks and are required to participate in a rehabilitation protocol. The standardized physiotherapy treatment protocol is adapted to the national guideline. During the first 6 weeks, patients are restricted to 0° external rotation and to no excentric force exercises for the first 3 months. Adherence to the rehabilitation protocol will be monitored during follow-up visits. No specific restrictions on concomitant care are imposed, except those outlined in the rehabilitation protocol.

Primary outcomes

The main study parameter is the shoulder function as measured by the Constant Murley Score (CMS). The CMS evaluates four aspects of the shoulder; two subjective: pain and activities of daily living and two objective: range of motion and strength.¹² The patient self-reported section can score up to 35 points and the objective section used by medical professionals can score up to 65 points, both adding up to a maximum of 100 points (best function). An adjustment to the score was described by Katolik et al. to incorporate any differences related to gender and age.²⁶ This adjusted CMS is described as a percentage, 100% being the highest possible score. Both values will be recorded. This will be measured during the 1-year follow up.

Secondary outcomes

Secondary study parameters include range of motion, Oxford Shoulder Score (OSS)^{4,13}, Subjective Shoulder Value (SSV)²⁵, Visual Analog Scale (VAS)¹⁵, Euro QoL 5 Dimensions questionnaire (EQ-5D)⁴⁷, Hospital Anxiety and Depression Scale (HADS)⁵³, Work-related questionnaire for upper extremity disorders (WORQ-UP)², Single-item Work Ability Score (WAS)²³ and implant survival. Regarding subjective assessment of function and pain, two questions were included. Both questions are a 7-scale assessment of general daily function and pain complaints when compared to the preoperative status (very much worse, much worse, a little worse, unchanged, a little improved, much improved, very much improved). To assess any evidence for subsidence or loosening of the implant, thorough radiologic measurements will be performed by a highly experienced radiologist at the periodic follow up, starting immediately postoperatively (baseline) and ending at 10 years postoperatively. Preoperative radiologic assessment will include glenoid morphology according to Walch⁵⁰, rotator cuff status and baseline offset measurements. Postoperative assessment will include thickness, location and gradation (according to Lazarus³⁰) of radiolucent lines; the glenoid seating grade according to Lazarus³⁰; implant position including offset, angulation and best-fit circle measurements; presence of osteolysis, migration, glenohumeral subluxation or dislocation and presence and location of heterotopic ossification and other calcifications. The endpoint for survival is the detection of loosening of the prosthesis on radiological imaging. Any adverse events or complications, whether related or unrelated to the implant, will be recorded and assessed systematically at each follow-up visit.

Sample size

In this non-inferiority study CMS will be used as the primary outcome measure. Based on a previous reported minimal clinically important difference (MCID) of 12.8 ± 2.5 points in anatomic shoulder arthroplasty at a mean 3.5 years follow-up, as reported by Simovitch et al.⁴⁶, the non-inferiority limit of the difference between the two designs was set at 10 points. If non-inferiority is proven, secondary testing for superiority will be performed. When the sample size in each group is 42 participants, a one-sided 0.025 significance-level t-test will have 80% power to reject the null hypothesis that the hybrid glenoid is inferior to the polyethylene glenoid by 10 points or more, in favor of the alternative hypothesis that the hybrid glenoid is non-inferior, assuming that the expected difference in means is 0 and the common standard deviation is 16.^{10,35} When considering a dropout of 10%, this will add up to a total of 94 patients (47 per group).

Statistical analysis

Patient demographics, clinical characteristics and radiographic outcome scores will be described according to their distributions. Continuous variables will be described as means with standard deviations (SD) in case of normal distribution, otherwise medians and interquartile ranges (IQR) will be used. Categorical variables will be described using frequencies with accompanying proportions. As this study has a non-inferiority design, analyses will be performed both Per Protocol and according to the Intention to Treat principle.

Primary non-inferiority analysis of the absolute CMS (defined as change from baseline) will be performed using linear regression analysis at the follow up moment of interest in order to correct for potential confounders. In case of confounding, adjustment will be performed by use of multivariate linear regression analysis. Non-inferiority analysis of the gender and age adjusted CMS (defined as change from baseline) will be performed in the same manner. Crude as well as adjusted differences between the treatment groups will be presented with 95% confidence interval (CI). In case the inferiority limit of -10 falls outside the lower bound of the 95% CI of the difference between the experimental and control group, non-inferiority is confirmed.

Additional mixed model analysis will be performed in case of repeated measurements, adjusted for confounders where necessary. Secondary PROMs will be analyzed by use of linear regression analysis or mixed model analysis and adjusted for potential confounders where necessary. Chi-squared tests will be performed in case of dichotomous variables (e.g. as complications). Additionally, revision rates will be calculated at 5 and 10 years follow up by use of Kaplan Meier (KM) analysis and compared by use of Log Rank tests. Cox proportional Hazard analysis will be performed to calculate Hazard ratios (HRs) with 95% CI, crude as well as adjusted for potential confounders (when necessary). Proportional Hazard assumption will be checked visually by use of Log minus Log plots. For all secondary analyses a p-value of 0.05 is considered statistically significant. Missing data will be handled using appropriate statistical methods, such as multiple imputation where applicable.

Recruitment status

Recruitment for this trial commenced in June 2025 and is currently ongoing. As of May 2026, 26 participants have been enrolled and randomized across the participating centers. The planned sample size is 94 participants, and recruitment will continue until the target sample size has been reached.

Discussion

This multicenter randomized controlled trial is designed to compare hybrid glenoid fixation with the commonly used cemented all-polyethylene component in anatomic total shoulder arthroplasty. Although hybrid designs have been rapidly adopted over the past decade, most available evidence is retrospective and varies considerably in follow-up duration and methodology.^{9,16,17,20,36} As a result, it remains unclear whether this widespread adoption translates into a clinically meaningful benefit for patients. This trial aims to address this evidence gap by providing high-quality, prospective, comparative data on both clinical and radiographic outcomes collected across three centers during a ten-year follow-up, using a single implant system with standardized surgical techniques and a uniform rehabilitation program.

Several retrospective level III studies have reported results of HG compared to PG. A recent retrospective comparison of 294 cemented keel, 527 cemented peg, and 981 hybrid cage glenoid components at a mean follow up of 65 months (range 24–217), showed significantly fewer complications, revisions, rates of aseptic loosening and radiolucent lines in the hybrid glenoid group when comparing to the other two groups.¹⁶ A retrospective comparison between 46 PG and 46 HG showed similar clinical outcome but decreased radiolucent lines in the HG group at minimum 2 year follow up.²⁰ Another retrospective study comparing 40 PG with 43 HG showed no significant difference at average 3.2 years of follow-up in terms of fixation, functional outcome, pain scores, and complications.²¹

An early HG design was withdrawn from the market in 2005 after alarming high revision rates of 21% due to fractures following implantation.⁹ This issue was resolved with the second-generation implant, as shown in a retrospective case series with 3.2 years of follow-up that reported no glenoid fractures and satisfactory clinical outcomes.³⁴ However, an Australian national registry study including 9332 aTSAs implanted from 2008 to 2023 comparing 4 different glenoid types showed increased revision rates when using a hybrid glenoid design, especially in the first year after implantation.¹⁸ A possible explanation mentioned in the report was soft-tissue failure due to potential overstuffing of hybrid glenoid implants. However, no definitive reason for revision was provided.

There are several limitations in this study. To enhance internal validity, strict inclusion criteria were used which can limit the generalizability of the findings of this study. Additionally, despite thorough preoperative evaluation, intraoperative findings may occasionally necessitate conversion to a stemmed or reverse prosthesis after randomization. Such post-randomization exclusions may introduce attrition bias and could affect the interpretation of the non-inferiority analysis. Although the non-inferiority margin was based on previously reported MCID values, the selection of this threshold remains partly arbitrary and may influence interpretation. Also, although patients and data analysts are blinded to treatment

allocation, blinding of the researcher during follow-up assessments may not always be feasible, which could introduce a risk of assessment bias.

Strengths of this protocol include its prospective controlled randomized design, broad set of validated outcome measures and long-term (10 year) follow-up. The shoulder specific outcome measures that were chosen are used frequently in arthroplasty research, which helps in comparing the results. Other included outcome measures are not frequently used in similar research but give valuable information on the general impact of these procedures on the general health and work-related functioning of patients. Lastly, standardized radiographic assessment at fixed intervals offers the opportunity to monitor subtle changes over time and may help clarify whether radiologic findings correlate with clinical symptoms or revision rates.

This randomized controlled trial will generate the first robust long-term comparative evidence on hybrid versus all-polyethylene glenoid components in stemless aTSA. This study will determine whether hybrid fixation offers a measurable clinical advantage by assessing differences in implant survival, radiographic loosening, function and patient reported outcomes. The results will directly support more evidence-based implant selection in daily practice.

Declarations

Data monitoring

A data monitoring committee is not considered necessary due to the low-risk nature of the intervention. Trial conduct will be monitored by the sponsor to ensure compliance with the study protocol and applicable regulations.

Ethics approval and consent to participate

This study will be conducted in accordance with the principles of the Declaration of Helsinki and its subsequent amendments. Ethical approval has been obtained from the Medical Ethics Review Committee of Amsterdam UMC, location AMC, the Netherlands (reference number: 2023.0616).

Written informed consent will be obtained from all participants prior to inclusion in the study.

Post-trial care

No specific post-trial care is planned beyond standard clinical follow-up.

Protocol amendments

Any important protocol modifications will be communicated to the relevant parties and updated in the trial registry.

Confidentiality

Participant data will be coded and handled confidentially in accordance with applicable data protection regulations (GDPR). Data will be stored in a secure, password-protected database accessible only to authorized study personnel.

Dissemination

Results of this study will be disseminated through peer-reviewed publications and presentations at scientific conferences. The results will also be reported in the clinical trial registry.

Consent for publication

Not applicable

Availability of data and materials

The datasets generated and/or analyzed during the current study are not publicly available due to privacy and ethical restrictions. De-identified data may be made available from the corresponding author on reasonable request, in accordance with applicable regulations and institutional policies. The full study protocol is available from the corresponding author on reasonable request.

Competing interests

A.v.N. reports research funding from LimaCorporate related to this study and consultancy for LimaCorporate. J.I.P.W., A.A.M., J.P.v.d.L., I.N.S., D.E., T.D.W.A. and M.v.d.B. declare that they have no competing interests.

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This study received research funding from LimaCorporate. The funding supports the conduct of the study but the funder has no role in study design, data collection, analysis, interpretation, or publication decisions.

Role of the sponsor and funders

The sponsor is responsible for the overall conduct of the trial and ensures compliance with applicable regulations, Good Clinical Practice (GCP), and ethical standards.

This is an investigator-initiated study. The principal investigator has received research funding from LimaCorporate related to the conduct of this study. However, LimaCorporate has no role in the design of the study, data collection, data analysis, data interpretation, or writing of the manuscript, and has no authority over the decision to submit the results for publication.

The sponsor has no role in data analysis or interpretation and does not influence the reporting of results.

Authors' contributions

J.I.P.W. drafted the manuscript and is the primary author of the protocol. A.v.N. conceived and initiated the study. I.N.S. developed the statistical analysis plan. A.A.M. contributed to writing the manuscript and will act as study coordinator. T.D.W.A. and A.v.N. will be responsible for patient inclusion. J.P.v.d.L., D.E., T.D.W.A., and M.v.d.B. critically reviewed the manuscript. All authors contributed to the study design, revised the manuscript critically for important intellectual content, and approved the final version of the manuscript.

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Not applicable

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Figures

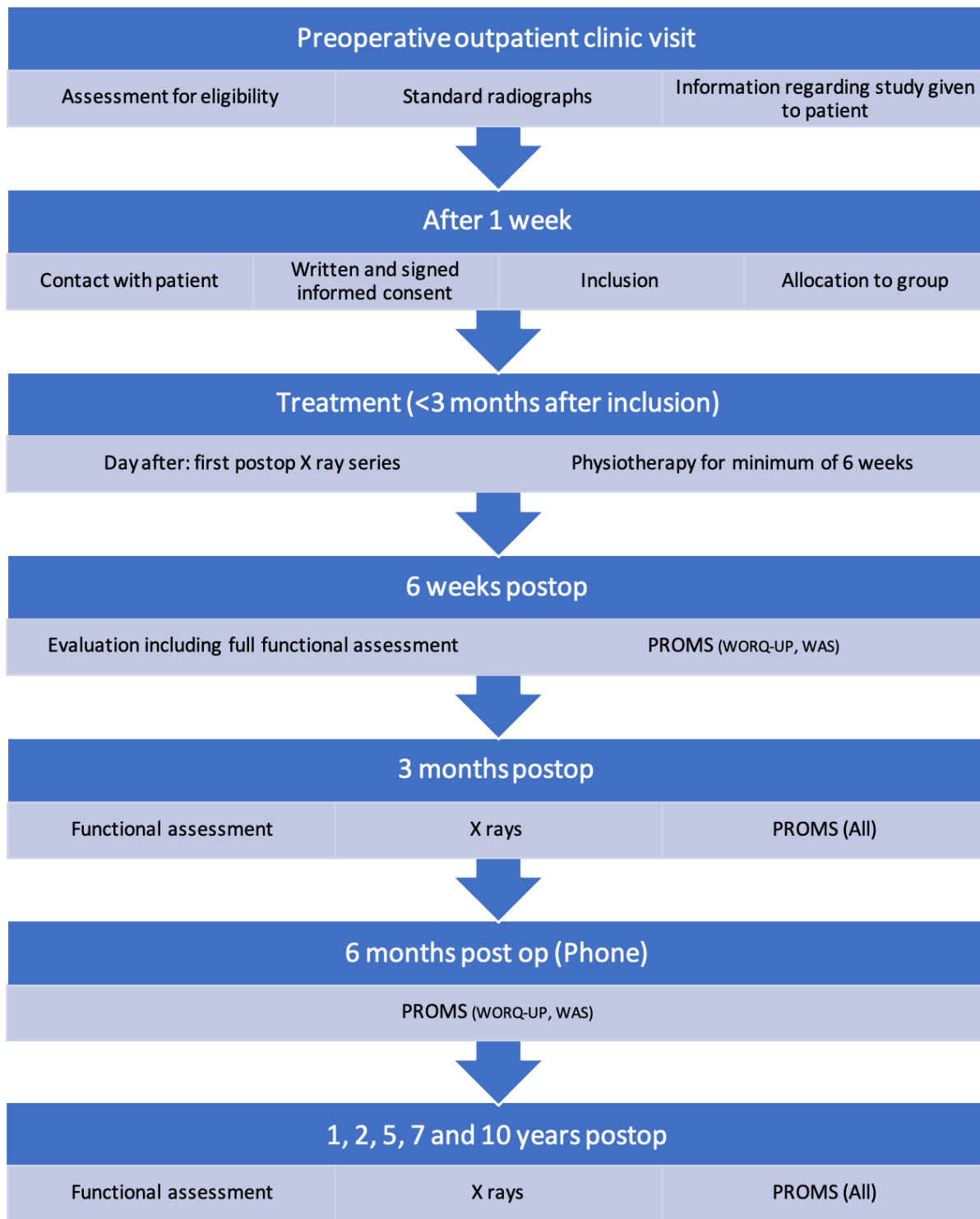


Figure 1

Overview of events