Does external femoral rotation on an AP-radiograph reduce the accuracy of preoperative planning of total hip arthroplasty?

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Does internal rotation of the femur on a plain AP radiograph lead to significantly more accurate preoperative digital planning of the femoral component in THA in comparison to external rotation?

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON48490

Source
ToetsingOnline

Brief title
Preoperative planning of total hip arthroplasty.

Condition

- Joint disorders

Synonym
Coxarthrosis, Osteoarthritis of the hip

Research involving
Human

Sponsors and support

Primary sponsor: Deventer Ziekenhuis

Source(s) of monetary or material Support: intern

Intervention

Keyword: digital, planning, rotation, THA

Outcome measures

Primary outcome

The main study parameter will be the proportion of agreement of femoral components planned for each of the externally rotated radiographs, compared to the *gold standard* (15-20o of internal rotation).

Secondary outcome

Difference between Patient Reported Outcome Measures (PROMs) before and 1 year after surgery per radiographical view.

Study description

Background summary

Preoperative digital planning is fundamental in the planning of total hip arthroplasty (THA) because it prepares the hip surgeon and his/her surgical team in the prediction of the type and size of the uncemented hip prosthesis most suitable for a particular patient. In addition, it facilitates anticipation on certain challenges, possibly reducing intraoperative complications and surgical time.

To execute the preoperative planning adequately it is essential to provide a proper and well-oriented Anterior-Posterior (AP) radiograph. Femoral rotation influences the appearance and dimensions of the proximal femoral canal but due to pain or impaired mobility, some patients are not able to rotate their leg internally as required according to the current protocols.

The purpose of this study is to determine if the standard radiograph in 15-20 degrees of internal femoral rotation provides the best accuracy of preoperative planning of THA. If so, it proves the importance of adhering to the current standard protocol despite practical difficulties. If not, the need to force patients who are unable to place their legs in internal rotation, would be less

relevant and radiographs could be adjusted to the patients ability to rotate their legs, without affecting the accuracy of digital planning.

Study objective

Does internal rotation of the femur on a plain AP radiograph lead to significantly more accurate preoperative digital planning of the femoral component in THA in comparison to external rotation?

Study design

Prospective single-center cohort study.

Study burden and risks

From each patient, we will obtain four different radiographs: one axial view with the feet in neutral (0°) position, one with the feet in 15 degrees of internal rotation (*gold standard*), and 15 and 30 degrees of external rotation. The estimated effective dose for a single AP pelvic radiograph is 70 mrem (0,7mSv) which makes the additional radiation exposure 2,1mSv for subjects enrolled in the study. There is no direct evidence for the additional amount of radiation to have any effect on human health. Patients will not benefit directly from participation in the study, as preoperative planning will be performed as usual.

Questionnaires for measurement of PROMs before and one year after surgery is done for every patient and therefore requires no extra effort from the patient.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Patients undergoing elective THA;
• Patients are able to place their foot exactly in the required positions for radiographs;
• Patients are over 18 years of age at the time of surgery;
• Patients who are capable, willing, and able to give informed consent for their participation in the study.

Exclusion criteria

• Patients undergoing a revision of a total hip arthroplasty;
• Patients who are unable to place their leg in the required positions;
• Patients who have a prosthesis in the contralateral hip, causing distortion on radiographs;
• Severe metabolic disorders that may impair bone formation or compromise the affected extremity which makes digital planning highly unreliable according to the operating surgeons* judgement;
• Patients who are unable to read and/or write in Dutch.

Study design

Design

Study type: Observational non invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-10-2021
Enrollment:	65
Type:	Actual

Ethics review

Approved WMO

Date:	12-11-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL68224.075.19