10 years survival of the cemented and uncemented total hip arthroplasty

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21463

Source
NTR

Brief title
Anatomic Benoist Girard, ABG, Cemented, uncemented THP, THA

Health condition

hip arthrosis, coxarthrosis, destruction of the cartilage layers, Post-traumatic arthritis

Sponsors and support

Primary sponsor: Department of Orthopaedic Surgery, Orbis Medisch Centrum, Sittard-Geleen, the Netherlands
Source(s) of monetary or material Support: Stichting ter bevordering van de orthopedische kwaliteit.

Intervention

Outcome measures

Primary outcome

Comparing the initial and long-term survival of the cemented and uncemented ABG prosthesis.
The primary endpoint will be defined as revision of the ABG THA for any kind. Revision for

prosthesis
related reasons (RPR) will be defined as revision for mechanical aseptic loosening, wear of the implant, breakage or instability due to implant failure that required surgical arthroplasty of femoral or acetabulum components.

Secondary outcome

Comparing the initial and long-term clinical results of the cemented and uncemented ABG prosthesis.
o Standard clinical parameters (Physical examination(2.4) and Questionnaires (2.5)) will be evaluated and compared between both groups.

Study description

Background summary

Total hip arthroplasty (THA) is often the end-stage treatment for severe osteoarthritis. Ageing and obesity are triggering factors for a higher number of patients with osteoarthritis. Osteoarthritis and overall joint pain is most located in the knees and hips. With the obesity and ageing in mind the incidence of a THA operation will be increasing, also in younger patients. Because of the younger aged patients who receive a THA the survival of the femoral component and articulations must be sufficient to give al long lasting quality of life and a minimal chance of revision of
the THA. There are two major ways to implant a THA, uncemented and cemented. The use of uncemented THA is increasing over de last years, but there is till so far no superior method. The Anatomic Benoist Girard (ABG) THA is made of a titanium alloy and has an anatomical femoral shape with only proximal fixation, the femoral component can be coated with hydroxyapatite for uncemented
fixation. In comparison to other femoral stems the ABG femoral stem has got a higher ‘shoulder’ for good contact and fixation on to the cancellous metaphyseal bone
and a smaller diaphyseal region to avoid diaphyseal fixation. Due to this specific geometry the physiological load transfer in both the acetabulum and femur is simulated. Fixation of the femoral and acetabular component can be uncemented
and cemented dependent on the surgeons experience or the intensity of the use of the THA. There is no difference in geometry
of the uncemented and cemented femoral components. The ABG THA has been widely used from 1989 in Europe and is also investigated in several studies. The study of Nourissat et al. showed a survival with revision as endpoint of 97.6%.
Nevertheless this was a study with a minimum 8-year follows up and had only investigated uncemented ABG THA. There are no studies comparing the long time follow up and survival, 10-years or more, of the
uncemented and cemented ABG THA. This clinical study is a benefit for patients who receive an ABG THA, if the survival rate turns out to be good for both uncemented and the cemented ABG THA in comparison with other prostheses, it would justify further use of both types of the

ABG THA.

Study objective

We hypothesize that there is no difference between the survival and follow of the uncemented and cemented ABG THA.

Study design

>10years Follow up

Intervention

The Anatomic Benoist Girard (ABG) THA is made of a titanium alloy and has an anatomical femoral shape with only proximal fixation, the femoral component can be coated with hydroxyapatite for uncemented fixation. In comparison to other femoral stems the ABG femoral stem has got a higher ‘shoulder’ for
good contact and fixation on to the cancellous metaphyseal bone and a smaller diaphyseal region to avoid diaphyseal fixation. Due to this specific geometry the physiological load transfer in both the acetabulum and femur is simulated. Fixation of the femoral and acetabular component can be uncemented
and cemented dependent on the surgeons experience or the intensity of the use of the THA. There is no difference in geometry of the uncemented and cemented femoral components

Contacts

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Eligibility criteria

Inclusion criteria

o Operated between January 2000 and December 2004
o Completed the full follow up
o Deceased with a known THA revision

Exclusion criteria

o Patients who did not completed the full follow up
o Deceased without a known THA revision

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2014
Enrollment:	800
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	12-02-2014
Application type:	First submission

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
NTR-new	NL4238
NTR-old	NTR4383
Other	14.009 : 14N03

Study results

Summary results

J Arthroplasty. 2015 Aug 29. pii: S0883-5403(15)00777-9. doi: 10.1016/j.arth.2015.08.023. [Epub ahead of print]
Results of Cemented Anatomically Adapted Total Hip Arthroplasty: A Follow-Up Longer Than 10years.
Heijnens LJ1, Schotanus MG1, Kort NP1, Verburg AD1, van Haaren EH1.