A comparative study of in-vivo wear between 28mm and 40mm metal heads with highly crosslinked (X3) acetabular polyethylene inserts in the hemispherical Trident cup.

Published: 07-10-2008
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This study investigates if there are differences in function and wear between total hip arthroplasty with standard or large diameter femoral heads.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON31891

Source
ToetsingOnline

Brief title
Large vs small femoral heads.

Condition

- Bone and joint therapeutic procedures

Synonym
Hip arthrosis

Research involving
Human

Sponsors and support

Primary sponsor: Stryker Howmedica
Source(s) of monetary or material Support: Stryker SA

Intervention

Keyword: function, head diameter, total hip arthroplasty, wear

Outcome measures

Primary outcome

Clinical outcome with focus on function using standard questionnaires and a

motion analysis measuring simple movements of daily living (e.g. gait).

Wear as femoral head penetration measured on conventional radiographs taken as

part of the clinical procedure anyway.

Secondary outcome

n.a.

Study description

Background summary

In total hip arthroplasty (THR) a metal femoral head runs in a polyethylene (PE) insert. Crosslinked PE has been proven to significantly reduce wear in-vivo. New generations of highly crosslinked PE (e.g. Stryker X3) have shown to reduce wear by >95% in simulator studies even independent femoral head diameter. Clinical studies have shown no measurable wear at 2 years.

Femoral heads with diameters larger than the standard size (28mm) restore more closely the natural anatomy and thus promise to reduce the luxation risk and in theory to improve post-op function or accelerate recovery.

Study objective

This study investigates if there are differences in function and wear between total hip arthroplasty with standard or large diameter femoral heads.

Study design

Multi-center prospective randomised comparison between patients receiving primary uncemented total hip arthroplasty either with a standard diameter or a large diameter metal femoral head. Randomization is performed using a designated computer software to assign patients to the study group (large heads) and control group (small, standard heads).

Intervention

n.a.

Study burden and risks

There is no known risk associated with study participation due to intervention as patients receive primary THR at state-of-the-art quality anyway.
There is no known risk associated with study participation due to measurements as the motion analysis only measures movements of daily living which are assessed by the doctor and physiotherapists as part of clinical follow-up anyway (e.g. gait). Wear measurement is performed on radiographs taken as part of clinical routine anyway.
Large diameter femoral heads promise benefits which require the clinical investigation as in this study.

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 indicated for uncemented primary total hip arthroplasty

Exclusion criteria

Patients who had a total hip arthroplasty on the contra-lateral side within the last year.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-11-2010
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	07-10-2008
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL22378.096.08