A prospective, multicenter, non-randomized, clinical outcome study of the R3 acetabular System in patients with degenerative hip disease.

Published: 17-09-2009
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Establish the non-inferiority of the R3 acetabular system with a high survival rate at 10 years fu (at least 90%). Second objective is to establish good clinical results by means of (Harris Hip Score, Hoos, UCLA and radiologic failures (like...

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

Summary

ID

NL-OMON47358

Source
ToetsingOnline

Brief title
Prospective R3 outcome study

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
osteoarthritis, reumatoid arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Smith & Nephew Orthopedics AG
Source(s) of monetary or material Support: Smith & Nephew Orthopaedics AG

Intervention

Keyword: Acetabular System, Non-randomized, Prospective, R3

Outcome measures

Primary outcome

Survival rate.

Secondary outcome

Harris Hip Score,

HOOS,

UCLA,

radiologic findings.

Study description

Background summary

The R3 acetabular system has the opportunity to choose whithin one system between metal-on-metal, ceramic-ceramic and oxinium-cross-linked polyethylene bearing combinations in total hip arthroplasty.

In the past metal on polyethylene wa the standard in total hip arthrplasty surgery. But due to the problems of polyethylene wear (with loosening of components as a result) new materials were developed (cross-linked polyethylene).
At this moment patients who require a total hip arthroplasty are much more active and are much younger.
The R3 system has been developed to fullfil this request for the young and active patient. The R3 system is made of stronger materials (like ceramic), less wear (cross-linked polyethylene) and suitable for the use of bigger heads to provide luxations.
Besides these benefits, the locking mechanism of the R3 system has been changed

in a way the insert is more easy to put in, gives more stability and therefore will initiate less wear.
The shell has a Stiktite coating which will provide a better possibility for bone ongrowhts. And therefore more stability of the shell itself and less migration.

Study objective

Establish the non-inferiority of the R3 acetabular system with a high survival rate at 10 years fu (at least 90%).

Second objective is to establish good clinical results by means of (Harris Hip Score, Hoos, UCLA and radiologic failures (like radiolucency) compared to other primary total hip systems through literature.

Study design

prospective, multicenter, non-randomized, clinical outcome study.

Study burden and risks

Not applicable

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

* Patient requires primary total hip arthroplasty due to non-inflammatory degenerative joint disease (e.g. osteoarthritis, post-traumatic arthritis, avascular necrosis, dysplasia/DDH) or inflammatory joint disease (e.g., rheumatoid arthritis)
* Patient has met an acceptable preoperative medical clearance and is free from or treated for cardiac, pulmonary, hematological, etc., conditions that would pose excessive operative risk
* The patient is willing to comply the follow-up schedule
Patient is 18-75 years old and he/she is skeletally mature

Exclusion criteria

* Patient has active infection or sepsis (treated or untreated)
* Patient is a prisoner or has an emotional or neurological condition that would pre-empt their ability or unwillingness to participate in the study including mental illness, mental retardation, linguistic insufficiencies (i.e. immigrants), or drug/alcohol abuse.
* Patients with acute hip trauma (femoral neck fracture)

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-11-2009
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	Total Hip prosthesis
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	17-09-2009
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-03-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL24088.094.08