

A prospective, multicenter, clinical outcome study of the NANOS neck preserving stem in patients with degenerative hip joint disease.

Published: 03-09-2010

Last updated: 01-05-2024

To prove that the NANOS prosthesis is a good prosthesis to be used in total hip replacement surgery, with low revision rate (< 10%) after 10 years. This percentage is known in the Swedish registry. Second objective is to prove that clinical...

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

Summary

ID

NL-OMON46912

Source

ToetsingOnline

Brief title

NANOS Prospective clinical outcome study

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym

osteoarthritis, reumatoid arthritis

Research involving

Human

Sponsors and support

Primary sponsor: Smith&Nephew, Inc

Source(s) of monetary or material Support: Bedrijf

Intervention

Keyword: Femoral Neck, NANOS, Non-randomized, Prospective

Outcome measures

Primary outcome

Survival rate at 10 years follow- up.

Secondary outcome

Clinical outcome: HHS, HOOS, UCLA and radiographic findings.

Study description

Background summary

Short-stemmed femoral shaft prostheses, have been introduced especially for younger patients. These endo-prostheses are anchored exclusively in the metaphysic and the proximal part of the diaphysis. Therefore, they are much shorter than the classic standard stems. Short femoral neck implants are claiming less interference with the biomechanics.

The NANOS femoral neck prosthesis has been developed based on clinical experience of various *short stem prostheses* and is the third generation of this type of prostheses. The implant requires only minimal bone resection. Therefore a maximum amount of bone is preserved. The cancellous bone around the metaphysic and the greater trochanter are retained to ensure load distribution and transfer.

The surface roughness of the titanium plasma coating on one hand increases the surface area and on the other hand ensures superior primary stability. The additional calcium phosphate coating allows accelerating the osseointegration process.

Study objective

To prove that the NANOS prosthesis is a good prosthesis to be used in total hip replacement surgery, with low revision rate (< 10%) after 10 years. This

percentage is known in the Swedish registry.

Second objective is to prove that clinical outcome (Harris Hip Score, HOOS, UCLA and radiological findings) is comparable to clinical results of other short stemmed femoral shaft prostheses, known from literature.

Study design

Prospective, multicenter, observational clinical outcome study.

Study burden and risks

This is an observational study with no extra interventions for the patients, as just completing one questionnaire which can be done while waiting to see the surgeon at control visits.

Contacts

Public

Smith&Nephew, Inc

Oberneuhofstrasse 10d
Baar 6340
CH

Scientific

Smith&Nephew, Inc

Oberneuhofstrasse 10d
Baar 6340
CH

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patients with degenerative hip disease, age 18-60, requiring a primary neck preserving hip arthroplasty (page 6).

Exclusion criteria

Previous failed endoprosthesis, active local or systemic infection, general health with ASA>2, pronounced femur neck angle of <125 or >145 degrees, insufficient bone stock (femur or acetabulum), proven osteoporosis, body mass index >30. (page 7).

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 11-07-2011

Enrollment: 50

Type: Actual

Ethics review

Approved WMO

Date: 03-09-2010

Application type: First submission

Review commission: METC Amsterdam UMC

Approved WMO

Date: 03-04-2018
Application type: Amendment
Review commission: METC Amsterdam UMC

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	NL30123.094.10