Randomized study using the BICON-PLUS cup with a modified surface treatment

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The primary objective is to assess if there are any differences in terms of Bone Mineral Density between patients receiving the BICON-PLUS NT with an alumina reduced device surface (study group) and a group of patients receiving the BICON-PLUS with...

Ethical review	Approved WMO
Status	Pending
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON30509

Source
ToetsingOnline

Brief title
RCT Bicon-Plus NT

Condition

- Joint disorders

Synonym
Coxarthrosis, wear of the hip joint

Research involving
Human

Sponsors and support

Primary sponsor: PLUS Endoprothetik AG
Source(s) of monetary or material Support: Plus Orthopedics AG;Erlenstrasse 4a;CH-6434 Rotkreuz

Intervention

Keyword: DEXA, RCT, Total Hip Arthroplasty

Outcome measures

Primary outcome

Postoperative bone minderal density (BMD)

Secondary outcome

- WOMAC (Western Ontario and McMaster Universities)

- Harris Hip Score

- Radiology: prevalence of radiolucent lines

Study description

Background summary

There is a need to develop a method that can reduce or eliminate the hard particles contaminating grit-blasted surfaces without affecting too much the overall topography.

Study objective

The primary objective is to assess if there are any differences in terms of Bone Mineral Density between patients receiving the BICON-PLUS NT with an alumina reduced device surface (study group) and a group of patients receiving the BICON-PLUS with the conventional surface (control group).
The secondary objective is to assess if there are any clinical and radiographic differences.

Study design

Randomized, double-blinded study

Intervention

- Total hip arthroplasty using a standard cup (Bicon-Plus)
- Total hip arthroplasty using a cup with a modified surface (Bicon-Plus NT)

Study burden and risks

- There will be 5 DEXA assessments (not performed in a normal clinical setting)
- The radiation dose from DEXA is very low (<<1 mSv). There is minimal risk attributable to these assessments.
- There is no specific risk from the physical assessment and the patient self-assessment.

Contacts

Public
PLUS Endoprothetik AG

Erlenstrasse 4a
6343 Rotkreuz
CH
Scientific
PLUS Endoprothetik AG

Erlenstrasse 4a
6343 Rotkreuz
CH

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Patients with primary or secondary osteoarthrosis
- Patients requiring primary arthroplasty

- Age at time of surgery: 50-70 years

Exclusion criteria

- Patients with rheumatoid arthritis
- Patients whose body mass index is higher than 35
- Patients requiring revision arthroplasty

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	31-03-2007
Enrollment:	50
Type:	Anticipated

Medical products/devices used

Generic name:	Bicon-Plus Cup
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	28-02-2007

Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)

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	NL15752.094.07