The reliability of a new guidance tool voor accurate cuppositioning in total hip arthroplasty

Published: 07-05-2013
Last updated: 24-04-2024

In deze studie zal de nauwkeurigheid van peroperatieve meting van de cuppositie door een nieuw ontworpen, onlangs gepatenteerd, meetinstrument worden onderzocht. In de toekomst kan, indien het meetinstrument betrouwbaar blijkt, peroperatief de...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON39661

Source
ToetsingOnline

Brief title
Guidewire trial

Condition

- Other condition
- Joint disorders

Synonym
arthrosis, osteoarthritis

Health condition

gewrichtskraakbeen

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: HipSecure b.v.

Intervention

Keyword: accuracy, cup, guidancetool, total hip arthroplasty

Outcome measures

Primary outcome

the difference of perioperative measured inclination and anteversion (by using

the device) compared to the values calculated on CT.

Secondary outcome

operating time, complications, such as: infection and pain at the entrancepoint

of the markingpoint.

Study description

Background summary

Osteoarthritis of the hip is one of the most common disease in Holland. About 257.400 people in the Netherlands are suffering from this disease. In the Isala Clinics about 700 primary total hip arthroplasties are performed each year. Because osteoarthritis is age related the demand for this procedure will increase. Joint replacing surgery is now world wide one of the most performed procedures. For this reason the occurence of complications should be kept to a minimum.

The most important complications are luxation, infection and loosening of components. Malposistioning of the cup is highly related to luxation and loosening of components.

The orientation of the acetabular component is defined in anteversion and inclination. Anteversion is the angle used to define the version of the opening of the cup to the front of the pelvis. Inclination is the angle which the cup forms with a horizontal line. Lewinnek defined a *safe zone* in which the cup would have an optimal position in the pelvis. This safe zone is defined as: 15

+/- 10 degrees anteversion and 45 +/- 10 degrees inclination. In this safe zone there is an optimal correlation between *range of motion* and stability of the prosthesis. Correct placement of the cup is usually difficult because of the absence of reliable intra-operative "landmarks". For this reason, about 50% of the cups are placed in a different position than the surgeon estimated while placing the cup during the procedure. It is clear that a method for more accurate cupposistioning is higly needed.

Study objective

In deze studie zal de nauwkeurigheid van peroperatieve meting van de cuppositie door een nieuw ontworpen, onlangs gepatenteerd, meetinstrument worden onderzocht. In de toekomst kan, indien het meetinstrument betrouwbaar blijkt, peroperatief de cuppositie op geleide van de metingen van het instrument worden aangepast en dus het postoperatieve complicatierisico verlagen.

In this study the accuracy of a new device will be tested for placement of the acetabular component in total hip arthroplasty. In the future this instrument can contribute to more accurate placement of the acetabular component, so the incidence of complications can be decreased.

Study design

prospective cohort study.

Intervention

placement of a screw in the pelvis, and increase of operationtime of approximately 10 minutes.

Study burden and risks

during the operation a screw is inserted in the bone. The screw is about 2 mm in diameter and is placed in the pelvis (Spina Iliaca Anterior Superior). . The depth of these pins in the bone is about 1 to 2.0 cm. the risk of this intervention can be expressed in postoperative pain and infection. A few days after the procedure a CT-scan will be made. This exposes the patient to some degree of radiation.

The benefit of participation is that the precise orientation of the actebularcomponent is known (CT-scan). This is of great importance for the prognosis of the implant. If malpostioning has occured we can instruct the patient so that the risk of complications can be reduced.

Contacts

Public
Isala Klinieken

Admiraal De Ruijterweg 395-2hg
amsterdam 1055mc
NL
Scientific
Isala Klinieken

Admiraal De Ruijterweg 395-2hg
amsterdam 1055mc
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

osteoarthritis of the hip

Exclusion criteria

obesity
hip dysplasia
traumatic hip injury
patients with increased risk for infection

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2013
Enrollment:	25
Type:	Anticipated

Medical products/devices used

Generic name:	insertion of a screw in the pelvis;on the screw a guidance tool will be attached
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	13-05-2013
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	NL42724.075.12