Three-dimensional cup orientation and pelvic tilt dynamics in primary total hip arthroplasty: a matched case-control study of unstable and stable hips.

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The hypothesis is that patients suffering a THA dislocation have a deviant 3-D cup orientation or pelvic tilt or both compared to patients with a stable THA.

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

Summary

ID

NL-OMON46678

Source
ToetsingOnline

Brief title
3DiCTIOn = 3-Dimensional Cup: Tilt and OrieNtation

Condition

- Joint disorders

Synonym
dislocated total hip arthroplasty

Research involving
Human

Sponsors and support

Primary sponsor: Diakonessenhuis Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: acetabular cup, pelvic tilt, total hip arthroplasty

Outcome measures

Primary outcome

The difference in 3-D acetabular cup orientation and pelvic tilt between

patients with a stable or unstable total hip arthroplasty.

Secondary outcome

Does not apply.

Study description

Background summary

There are differences in the orientation of the acetabular cup after placement of a total hip arthroplasty between patients. In addition, there are differences in the amount of pelvic tilt between patients. Both are of influence on relative component orientation of the total hip arthroplasty when a patients changes its position, for example from the standing to the sitting position. We think that these differences might be an important factor in patients suffering from a THA dislocation, therefore we want examine these factors between stable and unstable total hip arthroplasties.

Study objective

The hypothesis is that patients suffering a THA dislocation have a deviant 3-D cup orientation or pelvic tilt or both compared to patients with a stable THA.

Study design

A matched case-control study.

Study burden and risks

Both groups of patients will receive 1 extra lateral radiograph in the sitting position and a lateral radiograph in the standing position. The latter replaces the standard cross-lateral radiograph. The risk of the extra radiation dose in

case and control subjects in this age category can be valued as low to very low risk and can be considered as not harmful. There are no other known additional risks involved in this study. There are no extra visits necessary for particpating subjects.

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

- >65yrs
- Subjects presenting or presented with an dislocation of a THA at the emergency department and will or were treated by closed reduction
- Primary THA with known surgical approach and implants for treatment of hip osteoarthritis
- Sufficient cognitive and language (Dutch) skills
- Signed informed consent prior to inclusion.

- Control patients between 1-5 year after primary THA without instability.

Exclusion criteria

- previous contralateral THA
- indications for the THA other than primary coxarthrosis
- revision THA, unknown approach or unknown implants
- subjects with a neurologic disability (cognitive, psychiatric or mental disease)
- insufficient language skills
- not providing written informed consent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2019
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO

Date:	01-08-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL63363.041.17