Minimizing CT Radiation Dose in Total Hip Arthroplasty Patients using Iterative Model-Based Reconstruction.

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Primary objective: Minimizing and optimizing radiation dose while maintaining sufficient image quality in patients with THA. Secondary objective: Reducing metal artefacts and thus in addition further improving the overall image quality using O-MAR...

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

Summary

ID

NL-OMON42872

Source
ToetsingOnline

Brief title
Low dose CT

Condition

- Other condition
- Bone and joint therapeutic procedures

Synonym
Total hip artroplasty, total hip replacement

Health condition

Totale heuparthroplastiek

Research involving
Human

Sponsors and support

Primary sponsor: Philips Research
Source(s) of monetary or material Support: Philips Healthcare financiert de techniek en ondersteuning ter waarde van EUR 344.000;-

Intervention

Keyword: CT, Iterative model-based reconstruction, Low-dose, Metal artefacts

Outcome measures

Primary outcome

Main study parameters/endpoints: The main study parameters are a current standard care CT scan and an additional low-dose CT scan with 20%, 40%, 60% or 80% lowered radiation dose. The main endpoints are the objective and subjective image quality at different radiation dose levels for iterative reconstruction and model-based iterative reconstruction.

Secondary outcome

Secondary study parameters are metal artefacts. The secondary endpoints are objective and subjective image quality in conventional non-O-MAR images and O-MAR images.

Study description

Background summary

Rationale: In conventional computed tomography (CT), radiation dose and metal artefacts are two of the main obstacles limiting its wide use in musculoskeletal and orthopaedic imaging. Large metal implants in patients with total hip arthroplasty, cause severe metal artefacts, which strongly deteriorates image quality and significantly reduces the performance of CT in the detection of all sorts of prosthesis-related pathology, such as pseudo-tumours, capsular reactions and other soft tissue and bone pathologies. The orthopaedic metal artefact reduction algorithm O-MAR is an iterative metal

artefact reduction algorithm specially developed for CT-imaging of large metal orthopaedic implants. On the other hand, the use of model-based iterative reconstruction (IMR) techniques enables a significant reduction of radiation dose in various CT protocols while simultaneously improving overall image quality. The combined use of O-MAR and IMR in low-dose CT imaging will be optimized in a challenging population i.e. patients with large metal total hip arthroplasty (THA) by reducing radiation dose in four different patient groups with 20%, 40%, 60% or 80%.

Study objective

Primary objective: Minimizing and optimizing radiation dose while maintaining sufficient image quality in patients with THA.

Secondary objective: Reducing metal artefacts and thus in addition further improving the overall image quality using O-MAR.

Study design

Study design: Prospective diagnostic mono-centre study. Patients are randomly divided into four different groups and receive a standard care CT scan at 100% radiation dose and an additional low dose CT scan with 20%, 40%, 60% or 80% reduced radiation dose for respectively group 1, 2, 3 and 4.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The patient does not have benefit from participating in this study and will receive routine care. For research purposes an additional low-dose CT-scan is obtained for each patient. The additional low-dose CT-scan will be analysed after the study has been completed. This study will contribute to a lower radiation dose in future patients without compromising on diagnostic accuracy. In future, radiation dose will likely be reduced in other CT protocols also since we investigate dose reduction capabilities in one of the most challenging populations.

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

Patients with a unilateral or bilateral THA replacement.

Exclusion criteria

- No written informed consent
- Patient not meeting the inclusion criteria
- Previous participation in the study
- Pregnant women
- Concomitant participation in a study in which the patient is exposed to X-rays
- Patients younger than 40 years old

Study design

Design

Study type: Observational non invasive

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-09-2015
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	28-07-2016
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	NL58001.075.16