Iterative Model-Based Reconstruction on Cervical Spine CT: How low can you go?

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Achieving reduction of the radiation dose, while optimizing and improving image quality using IMR in CT-scans of the cervical spine.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bone and joint injuries
Study type	Observational non invasive

Summary

ID

NL-OMON46012

Source
ToetsingOnline

Brief title
Cervical spine CT, IMR

Condition

- Bone and joint injuries
- Fractures

Synonym
cervical spine injury, fracture

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: afdeling Radiologie Isala

Intervention

Keyword: cervical spine, computed tomography, MBIR, radiation dose

Outcome measures

Primary outcome

The main study parameters are the current standard CT-scan and an additional low-dose CT-scan with 40%, 60% or 80% lowered radiation dose. The main endpoint is the subjective image quality at different radiation levels for iterative reconstruction and model-based iterative reconstruction. The subjective image quality, scored by two radiologists, will be leading in the acceptance of low-dose CT images.

Secondary outcome

The secondary outcome measure is objective image quality at different radiation levels for iterative reconstruction and model-based iterative reconstruction. Hounsfield Units, noise, contrast-to-noise and signal-to-noise-ratios will be used to determine objective image quality.

Study description

Background summary

Following the advice of (inter)national guidelines, we implemented computed tomography (CT) as primary clearance tool in cervical spine trauma in our level I trauma center in Zwolle, The Netherlands. Since then the prevalence of fractures in cervical spine structures has more than doubled (increase of 110%). Along with a significant increase in fracture prevalence the mean exposure in mSv also increased significantly (83.7%). New Iterative Model-based Reconstruction algorithms like IMR (from Philips) are believed to contribute to a possible reduction of radiation necessary for sufficient and even improved image quality.

Study objective

Achieving reduction of the radiation dose, while optimizing and improving image quality using IMR in CT-scans of the cervical spine.

Study design

This study will be a prospective single-centre diagnostic cross-sectional cohort pilot-study. With the use of the NEXUS-criteria, trauma patients in need of imaging of the cervical spine are identified. Written informed consent will be requested before inclusion of the patient in the study. After written consent, patients are randomly divided into three different groups and receive a standard care CT at 100% radiation dose and an additional low dose CT scan with 40%, 60% or 80% reduced radiation dose.

Study burden and risks

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. We hypothesize that this study will contribute to a lower radiation dose in future patients without compromising on diagnostic accuracy.

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

- Subjects >= 50 years old
- NEXUS-criteria positive
- Written informed consent.

Exclusion criteria

- Hemodynamically unstable (hypotension < 90 mmHg)
- (Glasgow Coma Scale) EMV score < 15
- Previous participation in the study
- Pregnancy
- Intoxication (e.g. Alcohol, Drugs)
- Concomitant participation in a study in which the patient is exposed to X-rays
- History of psychiatric disorder which causes the patient to be incompetent to make a thought-out decision.

Study design

Design

Study type: Observational non invasive

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-09-2017
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	03-07-2017
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	NL61547.075.17