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Radiological issues in spinal immobilization

Submission date 16/07/2015	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 18/08/2015	**Overall study status** Completed	
Last Edited 04/08/2015	**Condition category** Musculoskeletal Diseases	

Plain English summary of protocol

Background and study aims
Patients who have been in an accident and are suspected of spinal injury are routinely treated with devices for spinal immobilization in order to stabilise the spinal column after injury and therefore prevent injury to the spinal cord. These devices are usually left in place while the patient is in the Emergency Room for assessment, including taking x-rays or making CT scans. However, the presence of these devices may hamper judgement of these images since they can produce artefacts (e.g. lines). Also, the presence of the devices may increase the amount of radiation the patient is exposed to. CT scanners and x-ray machines automatically adjust the radiation dose for imaging to get consistent image quality, and increase the dose when there is more matter (be it patient of device) to beam through. With this study we judge patient CT scans to assess image quality, and we measure radiation exposure using a phantom. We want to know which device therefore produces the best image quality and the least radiation exposure

Who can participate?
Adults (aged at least 18) than had a CT scan of their head while on a device for spinal immobilization in 2011.

What does the study involve?
Patients CT scans are assessed retrospectively for the presence and extent of artifacts caused by the spinal immobilization device used. Phantom CT scans and x-rays are assessed prospectively for radiation exposure in relation to the spinal immobilization device being used.

What are the possible benefits and risks of participating?
There are no benefits or risks to participants.

Where is the study run from?
Maastricht University Medical Center (Netherlands)

When is the study starting and how long is it expected to run for?
August 2013 to December 2014

Who is funding the study?
Maastricht University Medical Center (Netherlands)

Who is the main contact?
Miss Baukje Hemmes

Contact information

Type(s)
Scientific

Contact name
Miss Baukje Hemmes

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Netherlands
6228AK

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
METC 13-4-113

Study information

Scientific Title
Radiation exposure and objective and subjective image quality in spinal immobilization: a comparison of patient data and phantom data

Study objectives
Devices for spinal immobilization decrease image quality and increase radiation exposure

Ethics approval required
Old ethics approval format

Ethics approval(s)
METC MUMC (Medical Ethics Committee of the Maastricht University Medical Center), 19/12 /2013, ref: METC 13-4-113

Study design
1. Retrospective evaluation of CT scans of patients
2. Prospective evaluation of CT scans and x-rays of a phantom
3. Single center study

Primary study design

Observational

Secondary study design

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Radiation exposure and radiological image quality

Interventions
1. Patients CT scans are assessed retrospectively for the presence and extent of artifacts in relation to spinal immobilization device used.
2. Phantom CT scans and x-rays are assessed prospectively for radiation exposure in relation to spinal immobilization device used.

Intervention Type
Device

Primary outcome measure
1. Artifacts are scored independently by two trained judges, based on presence and impact of any disturbance of the image, which can be related back to the spinal immobilization device
2. Radiation exposure is measured using an ionisation chamber and electrometer
3. Noise is measured in SD of the CT values (in Hounsfield Units) of the pixels within 16 circular regions of interest covering 51% of the phantom using ImageJ

Secondary outcome measures
Overall assessment of the question which device for spinal immobilization performs best from a radiological point of view, with recommendations for clinical use.

Overall study start date
01/10/2013

Completion date
01/06/2015

Eligibility

Key inclusion criteria
Patients who underwent CT of the head in 2011 while on a device for spinal immobilization, aged 18 or older

Participant type(s)

Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
N/A

Key exclusion criteria
Patients are excluded when the type of device(s) used are unknown

Date of first enrolment
01/01/2014

Date of final enrolment
01/03/2014

Locations

Countries of recruitment
Netherlands

Netherlands Antilles

Study participating centre
Maastricht University Medical Center
Maastricht
Netherlands
6202AZ

Sponsor information

Organisation
Maastricht University Medical Center

Sponsor details

P. Debyelaan 25
Maastricht
Netherlands
6229HX

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02d9ce178

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Maastricht University Medical Center (Netherlands)

Results and Publications

Publication and dissemination plan
Results of the study will be offered for publication in peer reviewed international journals and for presentation at a national congress (Traumadagen [Dutch national trauma days]). We intend to offer the manuscript for publication as soon as ISRCTN registration is completed. We intend to give a presentation at the Traumadagen 2016.

Intention to publish date
01/09/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository