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Lowering the radiation dose in whole-body computed tomography of seriously injured patients using new imaging-processing software

Submission date
18/11/2013

Recruitment status
No longer recruiting

Registration date
16/12/2013

Overall study status
Completed

Last Edited
26/06/2020

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
We are conducting a study of 1000 patients with blunt penetrating major multiple trauma in order to compare two different methods of whole-body computed tomography (CT). This involves a native scan of the head and brain, and a contrast-enhanced scan of the neck and cervical spine, the chest, abdomen, and pelvis. Our objective is to find out whether CT using a lower than normal dose of radiation with an additional imaging software is as accurate and safe as the established CT scanning method. The findings may help to reduce unnecessary exposure to radiation for diagnostic purposes in severely injured patients while maintaining the proven diagnostic yield and therapeutic impact of the whole-body scan.

Who can participate?
Because of the specific condition, patients cannot be invited to participate in this study voluntarily. Most eligible patients will be unconscious and in a critical condition, demanding urgent diagnostics and often life-saving surgery.

What does the study involve?
A first group of 500 consecutive patients (men and women of all ages who, according to the trauma leader on call, are at risk of multiple trauma and need an immediate whole-body CT scan) will be imaged using the latest standard conventional dose protocol and a 128 multi-detector-row scanner.
The next group of 500 patients will undergo a dose-reduced protocol, using the iDoseTM (Philips, Eindhoven, The Netherlands) processing software.
All images will be re-read by independent experts, and compared to a synopsis of all findings collected during the study. We will determine the frequency of delayed diagnoses, the accuracy, and the radiation dose with either method. This study will mainly involve routine clinical and hospital data and we currently do not plan regular follow-up examinations.

What are the possible benefits and risks of participating?
This study mainly reflects routine care conditions. All patients will receive the current diagnostic standard care (whole-body CT in case of suspected major trauma). Patients in the normal-dose

group may benefit from a higher resolution of images and better detection of injuries, but also have a very small life-time risk of radiation-induced cancer. For patients in the reduced-dose group, certain injuries could be missed, but they are only exposed to a radiation dose which is close to natural radiation levels.

Where is the study run from?
The DoReMI study is conducted at the Unfallkrankenhaus Berlin (ukb), a high-volume supra-regional trauma center in Berlin, Germany.

When is the study starting and how long is it expected to run for?
The study will be initiated in December 2013, and recruitment will start in January 2014. Given the current caseload and patient numbers, the enrolment period will last about two years.

Who is funding the study?
This is an investigator-initiated study, and funding is provided by the Unfallkrankenhaus Berlin (ukb) (Germany).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DoReMI CIP V2.1 17-09-2013

Study information

Scientific Title
Dose Reduction in whole-body computed tomography (CT) scan evaluation of Multiple Injuries: a prospective cohort study with interrupted time-series analysis

Acronym
DoReMI

Study objectives
There is no difference between single-pass, whole-body 128-row multi-detector computed tomography (MDCT) at a low radiation dose using the iDose4 image processing algorithm (Philips, Eindhoven, The Netherlands) compared to conventional radiation dose MDCT with regard to:
1. The incidence of delayed diagnosis and delayed therapeutically relevant diagnosis until discharge
2. Diagnostic accuracy (in terms of sensitivity, specificity, positive and negative predictive value), as correlated to the reference standard of a synopsis of all subsequent clinical, imaging, surgical and autopsy findings
3. Patients safety
4. Radiation exposure (e.g., effective dose, volume CT dose index, dose-length-product)
5. General image quality (as independently assessed by two expert radiologists on a 100-mm visual analogue scale [VAS])
6. Objective image quality (e.g., contrast-to-noise ratio)
7. RNA/DNA instability/damage (to be used as a surrogate parameter)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Charité University Medical Centre, 11/11/2013, ref: EA2/048/13

Study design
Single-center prospective observational study with two consecutive cohorts of patients and interrupted time-series analysis

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Clinical evidence of or high suspicion of multiple trauma

Interventions
Cohort 1: Normal-dose single-pass, whole-body MDCT
Cohort 2: Low-dose, single-pass, whole-body 128-row multi-detector computed tomography (MDCT) with iDose image processing algorithm.

Apart from the different scanning methods, this study will be observational in any other aspect of clinical care.
We will use routine data to compose the reference test to verify index test findings. We currently do not plan study-specific follow-up of participants.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Incidence of delayed diagnosis and delayed therapeutically relevant diagnosis until discharge.

Co-primary outcome: Diagnostic accuracy (in terms of sensitivity, specificity, positive and negative predictive value), as correlated to the reference standard of a synopsis of all subsequent clinical, imaging, surgical and autopsy findings.

Secondary outcome measures
1. Patient safety
2. Radiation exposure (e.g. effective dose, volume CT dose index, dose-length-product)
3. General image quality (as independently assessed by two expert radiologists on a 100-mm visual analogue scale [VAS])
4. Objective image quality (e.g., contrast-to-noise ratio)
5. RNA/DNA instability/damage (to be used as a surrogate parameter)

Overall study start date
01/01/2014

Completion date
01/01/2016

Eligibility

Key inclusion criteria
We will collect data of all consecutive male and female patients of any age who:
1. Had been exposed to a high-velocity trauma mechanism (e.g., car crash, fall from height)
2. Present with clinical evidence or high suspicion of multiple trauma (predicted Injury Severity Score

[ISS] ≥16)
3. Re scheduled for primary, single-pass whole-body MDCT based on the decision of the trauma leader on call

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
500 eligible patients per cohort

Total final enrolment
1074

Key exclusion criteria
We will exclude patients who, at any time, withdraw consent of study participation.

Date of first enrolment
01/01/2014

Date of final enrolment
01/01/2016

Locations

Countries of recruitment
Germany

Study participating centre
Center for Clinical Research
Berlin
Germany
12683

Sponsor information

Organisation
Emergency Hospital, Berlin (Unfallkrankenhaus Berlin) (Germany)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/011zjcv36

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	03/03/2014		Yes	No
Results article	results	01/03/2020	26/06/2020	Yes	No