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Diagnostic efficacy and effectiveness of primary whole-body computed tomography (Pan-CT) in severe and multiple trauma

Submission date
30/08/2009

Recruitment status
No longer recruiting

Registration date
18/09/2009

Overall study status
Completed

Last Edited
26/04/2012

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
ukb/zkf_04/09

Study information

Scientific Title

Primary whole-body computed tomography (Pan-CT) for Trauma Resuscitation Evaluation: a prospective diagnostic effectiveness trial with a retrospective diagnostic accuracy study

Acronym
PATRES

Study objectives
Hypotheses (formulated as clinical rather than null-hypotheses):
1. Primary whole-body computed tomography (Pan-CT) is highly sensitive to exclude and highly specific to recognise life-threatening injuries in multiple trauma
2. Pan-CT significantly affects the clinical pre-test probability of certain injuries and influences clinical decision making

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Charité University Medical Centre in February 2009

Study design
PATRES-1: Retrospective diagnostic accuracy study
PATRES-2: Prospective observational diagnostic effectiveness study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Blunt and penetrating multiple trauma

Interventions
PATRES-1: Hospital charts and RIS/PACS data of the patients will be studied retrospectively to determine diagnostic accuracy of Pan-CT.

PATRES-2: Prospective observational study of patients undergoing Pan-CT. The diagnostic results will be assessed by comparing the initial clinical judgement, pre-test probability, and therapeutic plan of the trauma leader (an experienced trauma and orthopaedic surgeon who considers injury mechanism, clinical and ultrasound findings) immediately before Pan-CT, and after Pan-CT results.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
PATRES-1: Accuracy of Pan-CT (i.e. sensitivity, specificity, area under the ROC curve) for diagnosing i) multiple trauma, ii) individual injuries. A synopsis of all diagnoses obtained during

the hospital stay (e.g. CT-scans, clinical, intra-operative, and autopsy findings) will serve as the reference standard. All images will be re-read by experienced trauma radiologists, and hospital charts will independently be evaluated by trauma surgeons.
PATRES-2:
1. Shift in the pre-test probability of the prevalence and severity of injuries as judged by trauma surgeons prior to and after Pan-CT
2. Related changes in clinical decision making (e.g., emergency surgery, transfer to intensive care unit [ICU])

Key secondary outcome(s))
PATRES-1:
1. Rate of unnecessary CT-scans
2. Discrepancy between first and second readings

PATRES-2: Perceived value and effectiveness of CT-scans by trauma leaders (immediately after availability of CT-scans [i.e. at the trauma bay])

Completion date
31/12/2009

Eligibility

Key inclusion criteria
PATRES-1: Hospital charts and Radiology Information System/Picture Archiving and Communication System (RIS/PACS) data from consecutive male and female patients (no age limits) who i) had been admitted to the emergency department of a metropolitan trauma centre between 01/2008 and 06/2009 and ii) were referred to Pan-CT because of suspected multiple trauma by the physician on charge

PATRES-2: Trauma leaders caring for consecutive male and female patients (no age limits) who are admitted to the emergency department of a metropolitan trauma centre and are referred to Pan-CT because of suspected multiple trauma

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/09/2009

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
Germany

Study participating centre
Centre for Clinical Research
Berlin
Germany
12683

Sponsor information

Organisation
Unfallkrankenhaus Berlin Trauma Centre, Centre for Clinical Research (Germany)

ROR
https://ror.org/011zjcv36

Funder(s)

Funder type
Other

Funder Name
Investigator-initiated trial without commercial funding. Study logistics and personnel will be provided by the Centre for Clinical Research of the Unfallkrankenhaus Berlin (Germany), and related costs will be covered by the investigator.

Results and Publications

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?
Results article	retrospective cohort study results	09/12/2011		Yes	No