

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

Prospectively registered

Protocol

Registration date
18/09/2009

Overall study status
Completed

Statistical analysis plan

Results

Last Edited
26/04/2012

Condition category
Injury, Occupational Diseases, Poisoning

Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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 |