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

| Submission date | Recruitment status |
|---|---|
| 30/08/2009 | No longer recruiting |
| **Registration date** | **Overall study status** |
| 18/09/2009 | Completed |
| **Last Edited** | **Condition category** |
| 26/04/2012 | 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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

### Secondary study design
Other

### Study setting(s)
Hospital

### Study type(s)
Diagnostic

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

### 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 measure
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])

### Secondary outcome measures
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])

### Overall study start date
01/09/2009

### 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

**Age group**
Other

**Sex**
Both

**Target number of participants**
PATRES-1: n=600, PATRES-2: n=100

**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)

**Sponsor details**
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### Sponsor type
Hospital/treatment centre

### Website
http://www.ukb.de/de/main/home_2.htm

### 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

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