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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
30/08/2009		☐ Protocol		
Registration date 18/09/2009	Overall study status Completed Condition category	Statistical analysis plan		
		[X] Results		
Last Edited		Individual participant data		
26/04/2012	Injury, Occupational Diseases, Poisoning			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Dirk Stengel

Contact details

Centre for Clinical Research
Department of Trauma and Orthopaedic Surgery
Unfallkrankenhaus Berlin
Berlin
Germany
12683
+49 3056813030
dirk.stengel@ukb.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Warener Str. 7 Berlin Germany 12683 +49 3056813030 dirk.stengel@ukb.de

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