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One size does not fit all: is whole-body computed tomography beneficial for all patients with suspected major trauma?

Submission date
04/11/2025

Recruitment status
No longer recruiting

Registration date
05/11/2025

Overall study status
Completed

Last Edited
05/11/2025

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Whole-body computed tomography (WBCT) has become a common imaging tool for major trauma patients, potentially improving diagnostic speed and clinical outcomes. However, its benefits over conventional imaging protocol remain debated due to concerns such as increased radiation exposure and resource utilization. This study aimed to compare WBCT and conventional imaging in major trauma patients to assess differences in diagnostic efficiency, radiation exposure, and clinical outcomes.

Who can participate?
Patients aged 16 to 80 years admitted directly to our emergency department (ED) with major or multiple traumas

What does the study involve?
Participants were randomly allocated to either WBCT or conventional imaging (X-rays and CT scans). Data collected included demographics, injury severity, time intervals from arrival to diagnosis and decision-making, radiation dose, complications, and death rates.

What are the possible benefits and risks of participating?
Possible benefits:
1. Participants may receive faster or more comprehensive diagnostic imaging through WBCT, which could improve diagnostic efficiency and clinical decision-making.
2. The study could contribute to improved trauma care protocols in the future.
Possible risks:
1. WBCT involves higher radiation exposure compared to conventional imaging.
2. There is a small risk associated with contrast media (mild allergic reactions).
3. Transporting unstable patients to the CT room may pose minimal but recognized clinical risks; however, the hospital has established protocols to ensure safety.

Where is the study run from?
Chang Gung Memorial Hospital (Taiwan)

When is the study starting and how long is it expected to run for?
May 2011 to February 2012

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Erh-Hao Liu

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr I-Ming Kuo

Contact details
No.6, Sec.2
Jincheng Road.
Tucheng Dist.
New Taipei City
Taiwan
236
+886 (0)2 22630588 ext 6262
m7017@cgmh.org.tw

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Researchregistry11185

Study information

Scientific Title
One size does not fit all: is whole-body computed tomography beneficial for all patients with suspected major trauma? A prospective randomized controlled trial

Study objectives
Whole-body computed tomography (WBCT) has become a common imaging tool for major trauma patients, potentially improving diagnostic speed and clinical outcomes. However, its benefits over conventional imaging protocol remain debated due to concerns such as increased radiation exposure and resource utilization. This study aimed to compare WBCT and conventional imaging protocol in major trauma patients to assess differences in diagnostic efficiency, radiation exposure, and clinical outcomes.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 02/05/2011, The Institutional Review Board (IRB) of Chang Gung Memorial Hospital (No. 123, Dinghu Rd., Jiulu Village, Guishan District, Taoyuan City, 333, Taiwan; +886 (0)3-3196200 ext 3706; violet1202@cgmh.org.tw), ref: 98-3483A3

Study design
Prospective randomized controlled trial

Primary study design
Interventional

Study type(s)
Diagnostic, Efficacy, Treatment

Health condition(s) or problem(s) studied
Major trauma

Interventions
This study randomly assigned trauma patients to either a WBCT (whole-body CT) group or a conventional imaging group. All patients who met the selection criteria were referred to a randomization sheet. Each case was assigned a number in sequence and then allocated to the corresponding group based on the group label associated with that number on the sheet. The randomization sheet was created by printing lots (managed by Erh-Hao Liu) that were evenly distributed and labeled as either "experimental" or "control." Each number was assigned a group sequentially based on the order in which the lots were drawn.

The WBCT group received whole-body CT as the first-line imaging, while the control group underwent standard radiography and sonography, including FAST and plain films. Focused CT scans were used as needed based on initial findings. Both groups were further divided into three subgroups: unstable (with abnormal vital signs), unconscious (GCS <13 but stable vitals), and mechanism-related (stable and alert but with significant injury mechanisms). This design allowed for comparison of imaging strategies across varying trauma severities and patient conditions.

Intervention Type
Other

Primary outcome(s)
1. Pre-hospital time: time from the accident to the patient’s arrival at the ER
2. Resuscitation time: time from arrival at the ER to the completion of the primary survey and life-saving procedures
3. Complete primary imaging time: time from arrival to the completion of the first-line imaging study in each group
4. Final decision-making time: interval between arrival and disposition decision
5. Total ER stay time: total time from arrival to discharge from the ER
6. Complications, defined as in-hospital deterioration of organ function compared to the status at the time of the initial ED assessment
7. Diagnostic delays, defined as cases where additional diagnoses were made after admission or discharge that differed from the original diagnoses made in the ED, indicating a missed diagnosis

Key secondary outcome(s))
Subgroup analyses comparison: Unstable, Unconscious, and Mechanism-related groups

Completion date
21/02/2012

Eligibility

Key inclusion criteria
Patients admitted directly to our emergency department (ED) who met the trauma team activation criteria were considered candidates for major or multiple traumas. The criteria included one or more of the following:
1. Unstable vital signs:
1.1. Systolic blood pressure <90 mmHg
1.2. Respiratory rate >29 or <10
2. Conscious disturbance:
2.1. Glasgow Coma Scale (GCS) <13
3. Trauma mechanisms:
3.1. Falls from a height >6 meters
3.2. Pedestrian struck by a vehicle
3.3. Heavy object crush injury
3.4. Ejection from a vehicle
3.5. Death of another passenger in the same event
3.6. Extreme age (<10 or >65 years) in cases of multiple trauma

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Upper age limit
80 years

Sex
All

Total final enrolment
151

Key exclusion criteria
1. Under 16 years of age
2. Pregnant
3. Referrals from other hospitals

4 .Suspected of drowning
5. Experiencing traumatic cardiac arrest (TCA) without return of spontaneous circulation (ROSC)
6. Solitary burn injuries
7. Clearly isolated focal injuries

Date of first enrolment
02/05/2011

Date of final enrolment
21/02/2012

Locations

Countries of recruitment
Taiwan

Study participating centre
Chang Gung Memorial Hospital
No. 123, Dinghu Road
Jiulu Village
Guishan District
Taoyuan City
Taiwan
333

Sponsor information

Organisation
Linkou Chang Gung Memorial Hospital

ROR
https://ror.org/02dnn6q67

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The data supporting this study contain sensitive personal information and cannot be made publicly available. Data may be shared by the corresponding author upon reasonable request and with appropriate ethical approval.

IPD sharing plan summary
Available on request