REACT-2; Randomized study of the early assessment by CT scanning in trauma patients

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To compare the effects of the rapid and detailed information of organ and tissue injury from primary *total body* CT scanning with standard conventional ATLS based radiological imaging during the primary survey, on clinical outcome and long term...

Ethical review	-
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON37113

Source ToetsingOnline

Brief title

Primary total body CT scanning in severely injured trauma patients

Condition

• Other condition

Synonym trauma injury

Health condition

ernstige traumatische letsels

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum **Source(s) of monetary or material Support:** subsidieaanvragen zijn momenteel in behandeling bij ZonMw

Intervention

Keyword: Computed Tomography, trauma, whole-body

Outcome measures

Primary outcome

The in-hospital mortality

Secondary outcome

- The difference in mortality: the 24hour mortality and the mortality during

the first year after the trauma.

- The difference in morbidity: the complications and total number of

re-interventions

and re-admissions during the first year after the trauma.

- The difference in hospital time: the length of in-hospital and ICU stay and

the total

number of ventilation days.

- The difference in quality of life 6 and 12 months after the trauma as

recorded by

filling in two questionnaires (HUI-3 and EuroQoL).

- The difference in ratio of non-operative management strategies: i.e.

conservative

and angio-interventional treatment versus primary operations.

- The difference in radiation exposure between total body CT and standard

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work-up.

- The difference in diagnostic time and between total body CT and standard work-up.

- The difference in cost-effectiveness (measured by a patient questionnaire

derived from the Dutch Labour and Health Questionnaire and adapted for

international use 3 and 6 months after the trauma).

- The difference in diagnostic accuracy between total body CT and standard

work-up.

Study description

Background summary

Trauma is a major cause of mortality and morbidity throughout the world, especially in the younger people below the age of 50 years. In the Netherlands annually 990.000 patients visit the emergency department (ED) after an injury and 5300 people die after an accident. Time, accuracy and specificity are of great importance in evaluating trauma patients before further treatment is planned. The ongoing development of modern imaging techniques makes them both faster and more accurate. Nowadays, imaging techniques become increasingly more available in the emergency department or trauma resuscitation room itself. With these technical and infrastructural improvements, the current (imaging) guidelines according to the ATLS may not represent the optimal primary imaging algorithm anymore. Especially Computed Tomography (CT) has evolved as a reliable and important method of diagnostic imaging in trauma. Both (solid) organ and osseous injuries can be diagnosed and (life-threatening) bleeding sites can be identified. The CT scanners used to be too time consuming and usually have been located at other departments of the hospital. Modern CT scanners are fast and more frequently available in the ED. This allows fast and detailed diagnoses for well-founded planning of further therapy.

Study objective

To compare the effects of the rapid and detailed information of organ and tissue injury from primary *total body* CT scanning with standard conventional ATLS based radiological imaging during the primary survey, on clinical outcome

and long term effects on Quality of Life of severely injured trauma patients.

Study design

A multicenter prospective randomized trial in several Level-1 trauma centers; with a CT scanner located in the trauma resuscitation room or emergency Department. The *total body CT scan* group will only receive a *total body* CT scan in the primary survey and the conventional group will be evaluated according to the local conventional trauma protocol (based on the ATLS guidelines).

Intervention

the total body CT scan without prior conventional imaging

Study burden and risks

All patients will receive optimal trauma care. Patients who are presented in our trauma resuscitation room will either get a primary *total body* CT scan or will be evaluated according to our conventional ATLS guidelines based protocol. Because any patient can be withdrawn at any moment from this study protocol by the leading trauma surgeon or anaesthesiologist there are no extra risks for the patient.

If there are two trauma patients presented at the same time the latter patient will be excluded and evaluated according to our conventional protocol in another trauma room with bucky equipment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

At least one of the following parameters at hospital arrival:

- respiratory rate *30 or *10, or
- pulse *120/min
- systolic blood pressure *100 mmHg
- exterior blood loss *500 ml
- Glasgow Coma Score *13 or abnormal pupilary reaction on site.;Or one of the following clinically suspicious diagnoses:
- Patients with signs of fractures from at least two long bones
- Patients with clinical signs of flail chest, open chest or multiple rib fractures
- Patients with clinical signs of severe abdominal injury
- Patients with a clinically evident pelvic fracture
- Patients with signs of unstable vertebral fractures or signs of spinal cord compression;Or one of the following injury mechanisms:
- fall from height (>3 meters / > 10 feet)
- ejection from the vehicle
- death occupant in same vehicle
- severely injured patient in same vehicle
- wedged or trapped chest / abdomen

Exclusion criteria

- Age <18 years (if known)
- Known pregnancy
- Patients referred from other hospitals

- Any patient with a penetrating head / neck injury (except gun shot wounds) as the clearly isolated injury as judged by the trauma leader

- Any patient who is judged to be too unstable to undergo a CT scan and requires

(cardiopulmonary) resuscitation or immediate operation because death is imminent, according to the trauma team leader in mutual agreement with the other leading care givers.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

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NL	
Recruitment status:	Recruiting
Start date (anticipated):	20-04-2011
Enrollment:	450
Туре:	Actual

Ethics review

Not available

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register CCMO ID NL21352.018.08