A multicenter, randomized study of early assessment by CT scanning in severely injured trauma patients.

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Trauma is a major cause of mortality and morbidity throughout the world, especially in younger people. Time, accuracy and specificity are of great importance in diagnostic imaging of severely injured trauma patients. Especially Computed Tomography (...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27189

Bron
Nationaal Trial Register

Verkorte titel
REACT-2 trial

Aandoening

Computed Tomography (CT) scanning
Total body CT
Trauma
Trauma resuscitation room
Primary survey

CT
Totale lichaam CT
Trauma
Traumakamer
Trauma-opvang

Ondersteuning

Primaire sponsor: Academic Medical Center.
Overige ondersteuning: -

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

In-hospital mortality.

Toelichting onderzoek

Achtergrond van het onderzoek

Literature provides limited evidence whether immediate ‘total body’ CT (TBCT) leads to a better clinical outcome in severely injured trauma patients then conventional radiographic imaging (i.e X-rays with FAST ultrasound) supplemented with selective CT scanning. The aim of the REACT-2 study is to compare these two imaging strategies.

An international, multicenter randomized clinical trial will be conducted. Participating trauma centers have a multi-slice CT scanner located in the trauma resuscitation room or Emergency Department. Adult, non-pregnant, severely injured trauma patients according to well defined fysiological or clinical criteria will be included. Patients in whom immediate CT scanning will hamper cardiopulmonary resuscitation or who require an immediate operation because of imminent death (both as judged by the trauma team leader) are excluded.

The intervention group will receive a TBCT scan (head to pelvis) during the primary survey. The control group will be evaluated according to local conventional trauma imaging protocols (based on ATLS guidelines) with selective CT scanning. Possible interventions during the primary survey consist of intubation or performing a cricothyrotomy, chest tube insertion or pericardiocenthesis and taking hemorrhage controlling measurements such as applying a pelvic binder or external pressure on bleeding sites.

Primary outcome will be in-hospital mortality. Secondary outcomes include differences in

mortality and morbidity during the first year post trauma, general health at 6 and 12 months post trauma, several clinically relevant time intervals and differences in radiation exposure and cost-effectiveness.

Doel van het onderzoek

Trauma is a major cause of mortality and morbidity throughout the world, especially in younger people. Time, accuracy and specificity are of great importance in diagnostic imaging of severely injured trauma patients. Especially Computed Tomography (CT) has evolved as a reliable and important method of diagnostic imaging in trauma. With recent technical and infrastructural improvements in radiologic imaging, the current (imaging) guidelines such as the ATLS may not represent the optimal primary imaging algorithm anymore.

Hypothesis: Immediate ‘total body’ CT scanning during the primary survey of severely injured trauma patients has positive effects on patient outcome compared with standard conventional ATLS based radiological imaging supplemented with selective CT scanning.

Onderzoeksopzet

Nov '10 - Mar '11: Preparation;

Apr '11 - Dec '13: Inclusion period;

Jan '14 - Mar '12: First data analysis/reporting;

Jan '14 - Jun '14: Completing follow-up;

Jul '14 - Aug '14: Final analysis/reporting.

Onderzoeksproduct en/of interventie

Immediate ‘total body’ CT scan without preceding conventional radiography (i.e. X-rays and FAST ultrasound).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Trauma patient with presence of one of the following criteria:

At least one of the following parameters at hospital arrival:

1. Respiratory rate ≥30/min or ≤10/min;

2. Pulse ≥120/min;

3. Systolic blood pressure ≤100 mmHg;

4. Estimated external blood loss ≥500 ml;

5. Glasgow Coma Score ≤13;

6. Abnormal pupillary light reflex on site.

Or clinical suspicion of one of the following diagnoses:

1. Patients with signs of fractures from at least two long bones;

2. Patients with clinical signs of flail chest, open chest or multiple rib fractures;

3. Patients with clinical signs of severe abdominal injury;

4. Patients with a clinically evident pelvic fracture;

5. Patients with signs of unstable vertebral fractures or signs of spinal cord compression.

Or one of the following injury mechanisms:

1. Fall from height (>3 meters / > 10 feet);

2. Ejection from the vehicle;

3. Death occupant in same vehicle;

4. Severely injured patient in same vehicle;

5. Wedged or trapped chest / abdomen.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Age <18 years (if known);

2. Known pregnancy;

3. Patients referred from other hospitals;

4. Clearly low energy trauma with blunt injury mechanism;

5. Any patient with a penetrating head / neck injury (except gun shot wounds) as the clearly isolated injury;

6. 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.
Inclusion criteria and exclusion criteria are decided upon by trauma team leader in mutual agreement with the other relevant trauma team members.

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	20-04-2011
Aantal proefpersonen:	1078
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	17-11-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2490

Register	ID
NTR-old	NTR2607
Ander register	METC AMC : 10/145
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

Saltzherr TP, Jin PH, Bakker FC, Ponsen KJ, Luitse JS, Scholing M, Giannakopoulos GF, Beenen LF, Henny CP, Koole GM, Reitsma HB, Dijkgraaf MG, Bossuyt PM, Goslings JC. An evaluation of a Shockroom located CT scanner: a randomized study of early assessment by CT scanning in trauma patients in the bi-located trauma center North-West Netherlands (REACT trial). BMC Emerg Med. 2008 Aug 22;8:10

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Fung Kon Jin PH, Penning N, Joosse P, Hijdra AH, Bouma GJ, Ponsen KJ, Goslings JC. The effect of the introduction of the Amsterdam Trauma Workflow Concept on mortality and functional outcome of patients with severe traumatic brain injury. J Neurotrauma. 2008 Aug; 25(8):1003-9.

Fung Kon Jin PH, Goslings JC, Ponsen KJ, van Kuijk C, Hoogerwerf N, Luitse JS. Assessment of a new trauma workflow concept implementing a sliding CT scanner in the trauma room: the effect on workup times. J Trauma. 2008 May;64(5):1320-6.