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

No registrations found.

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|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON27189

**Source**
Nationaal Trial Register

**Brief title**
REACT-2 trial

**Health condition**

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

CT
Totale lichaam CT
Trauma
Traumakamer
Trauma-opvang

### Sponsors and support

**Primary sponsor:** Academic Medical Center.
**Source(s) of monetary or material Support:** -

## Intervention

## Outcome measures

### Primary outcome

In-hospital mortality.

### Secondary outcome

1. Mortality and morbidity during the first year post trauma;

2. General health at 6 and 12 months post trauma;

3. Several clinically relevant time intervals;

4. Differences in radiation exposure;

5. Differences in cost-effectiveness.

# Study description

### Background summary

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.

**Study objective**

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.

**Study design**

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.

**Intervention**

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

# Contacts

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# Eligibility criteria

## Inclusion criteria

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.

### Exclusion criteria

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.

## Study design

### Design

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 20-04-2011 |
| Enrollment: | 1078 |
| Type: | Actual |

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion

| | |
|---|---|
| Date: | 17-11-2010 |
| Application type: | First submission |

## 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 | ID |
|---|---|
| NTR-new | NL2490 |
| NTR-old | NTR2607 |
| Other | METC AMC : 10/145 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Study results

**Summary results**

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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Saltzherr TP, Goslings JC; multidisciplinary REACT 2 study group. Effect on survival of whole-body CT during trauma resuscitation. Lancet. 2009 Jul 18;374(9685):198
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Saltzherr TP, Beenen LF, Reitsma JB, Luitse JS, Vandertop WP, Goslings JC. Frequent Computed Tomography Scanning Due to Incomplete Three-View X-Ray Imaging of the Cervical Spine. J Trauma. 2009 Dec 15.
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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.
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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.