# Randomized study of Early Assessment by CT scanning in Trauma patients.

No registrations found.

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

## Summary

### ID

NL-OMON22108

**Source**
NTR

**Brief title**
REACT Trial

**Health condition**

Acute traumatische letsels, veroorzaakt door externe oorzaken

### Sponsors and support

**Primary sponsor:** Trial Coordinator REACT-trial
Drs. P.H.P. Fung Kon Jin, G4-137
Postbus 22660
1100 DD Amsterdam
the Netherlands
p.fungkonjin@amc.uva.nl
tel: 020-5666626
**Source(s) of monetary or material Support:** Geneeskundige Hulp bij Ongevallen en Rampen (GHOR) De witte kolom in het eerste uur

ZonMw
Sophieke van Ginkel, programmasecretaris
Laan van Nieuw Oost Indië 334
Postbus 93245
2509 AE Den Haag

the Netherlands
tel: 070-3495127

## Intervention

## Outcome measures

### Primary outcome

The number of days spent outside the hospital in the first year following the emergency admission in the shockroom will be our primary outcome. This outcome is responsive to differences in mortality (no more/additional days outside hospital), to differences in hospital stay for the initial admission, to differences in readmission rate (i.e. because of missed diagnoses).
Furthermore, there is a positive association between a shorter hospital stay and better functional health. Care will be given to harmonize discharge criteria between the two hospitals.

### Secondary outcome

The secondary outcome parameters for the patient outcome part of the study will focus on:

1. The process of care parameters of the initial admission. This will include the comparison of various time intervals relevant in trauma care:

1.1 time to obtain results of CT imaging;

1.2 time to operation or other interventions (door-to-treatment time);

1.3 time to active bleed managing;

1.4 time to definitive care facility (ICU, high care, nursing ward);

1.5 duration of intensive care treatment;

1.6 time to discharge from the hospital;

2. Radiological examinations and findings:

2.1 The frequency and type of radiological examinations in each strategy;

2.2 description of the number, type and severity of diagnoses categorized by imaging modality in each strategy;

3. General health. This will be measured in all patients at 6 and 12 months after the shockroom admission using the EuroQol and HUI3 questionnaires;

4. All-cause mortality. This will include both in-hospital mortality and mortality during the first year following the trauma;

5. Radiation dose. The mean radiation dose will be calculated in both strategies based on the actual number and type of radiological examinations related to the initial trauma performed in each patient during the first year.

# Study description

**Background summary**

Background:

Trauma is a major source of death and morbidity, especially in people below the age of 50 years. In the Netherlands yearly 5,100 people die from accidents and 980,000 people visit an Emergency Department because of an injury. The use of CT scanning has gained wide acceptance in the evaluation of trauma patients and provides detailed information on location and severity of injuries. While rapid diagnosis and treatment are of paramount importance in trauma patients, CT scanning is frequently time consuming due to logistical (location of CT scanner elsewhere in the hospital) and technical issues. In one of two locations of the Northwest-Netherlands Trauma Center an innovative and unique infrastructural change has been made in which the CT is transported to the patient instead of the patient to the CT scanner. Such a new concept is (worldwide) currently only available in the Academic Medical Center in Amsterdam. Early shockroom CT scanning provides an all-inclusive multifocal diagnostic modality that can detect (potentially life-threatening injuries) in an earlier stage, so that therapy can be directed based on these findings.

Aim:

To assess the effect of a strategy involving early shockroom CT scanning with a standard diagnostic imaging strategy in trauma patients on both patient outcome and operations research.

Study design:

Prospective, randomized trial, comparing the two level-1 trauma centers VUmc and AMC.

Population:

All trauma patients that are transported to the AMC or VUmc shockroom according to the current prehospital triage system. Exclusion criteria are patients younger than 16 years of

age, patients who die during transport, and patients (or close relatives) who decline transportation.

Intervention:

Patients are transported to either the VUmc or the AMC, based on randomization. Trauma care will remain the same for both institutions, with the only difference the location of the CT scanner.

Endpoints:

Patient outcome in both strategies will be compared using the number of days outside the hospital during the first year following the trauma as the primary outcome measure. Secondary outcomes include general health (EuroQol) at 6 and 12 months post trauma, mortality and morbidity, and various time intervals of the initial evaluation relevant to trauma care.

### Study objective

A trauma care strategy involving early shockroom CT scanning with a standard diagnostic imaging strategy in trauma patients has a positive effect on both patient outcome and operations research.

### Study design

N/A

### Intervention

Patients are transported to either the VUmc or the AMC, based on randomization. Trauma care will remain the same for both institutions, with the only difference the location of the CT scanner.

## Contacts

**Public**
Academic Medical Center (AMC), G4-105,
P.O. Box 22660

J.C. Goslings
Meibergdreef 9
Amsterdam 1100 DD

The Netherlands
+31 (0)20 5666019
**Scientific**
Academic Medical Center (AMC), G4-105,
P.O. Box 22660

J.C. Goslings
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5666019

# Eligibility criteria

## Inclusion criteria

All patients that are transported to the AMC or VUmc shockroom according to current pre-hospital triage system based on:

1. Injury mechanism;

2. Revised Trauma Score;

3. Presence or absence of traumatic brain injury.

## Exclusion criteria

Excluded from analysis and comparison are:

1. Patients younger than 16 years of age;

2. Death during transport to the hospital.

# Study design

## Design

Study type: Interventional

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-11-2005 |
| Enrollment: | 1124 |
| Type: | Actual |

## Ethics review

Positive opinion

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|---|---|
| Date: | 05-08-2005 |
| 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 | NL57 |
| NTR-old | NTR86 |
| Other | ZON-MW : 3920.0005 |
| ISRCTN | ISRCTN55332315 |

# Study results

**Summary results**
N/A