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Randomised study of Early Assessment by CT scanning in Trauma patients

Submission date	Recruitment status
12/09/2005	No longer recruiting
Registration date	**Overall study status**
12/09/2005	Completed
Last Edited	**Condition category**
02/05/2012	Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.reacttrial.nl

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

ZON-MW 3920.0005

Study information

Scientific Title

Acronym
REACT Trial

Study objectives
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.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Trauma

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

Intervention Type
Other

Phase
Not Specified

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

- The process of care parameters of the initial admission. This will include the comparison of various time intervals relevant in trauma care:
1. time to obtain results of CT imaging
2. time to operation or other interventions (door-to-treatment time)
3. time to active bleed managing
4. time to definitive care facility (ICU, high care, nursing ward)
5. duration of intensive care treatment
6. time to discharge from the hospital

- Radiological examinations and findings:
1. the frequency and type of radiological examinations in each strategy
2. description of the number, type and severity of diagnoses categorized by imaging modality in each strategy

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

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

- 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.

Overall study start date
01/11/2005

Completion date
01/05/2007

Eligibility

Key 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

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
1,124

Key exclusion criteria
Excluded from analysis and comparison are:
1. Patients younger than 16 years of age
2. Death during transport to the hospital

Date of first enrolment
01/11/2005

Date of final enrolment
01/05/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Trauma Unit AMC, G4-105
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Sponsor information

Organisation
Academic Medical Center (AMC) (The Netherlands)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Research council

Funder Name
The Netherlands Organization for Health Research and Development (Zon-Mw) (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	1. study protocol	22/08/2008		Yes	No
Results article	results	01/01/2012		Yes	No