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

Gepubliceerd: 05-08-2005 Laatst bijgewerkt: 13-12-2022

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.

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

Samenvatting

ID

NL-OMON22108

Bron
NTR

Verkorte titel
REACT Trial

Aandoening

Acute traumatische letsels, veroorzaakt door externe oorzaken

Ondersteuning

Primaire sponsor: Trial Coordinator REACT-trial
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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Excluded from analysis and comparison are:

1. Patients younger than 16 years of age;

2. Death during transport to the hospital.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-11-2005
Aantal proefpersonen:	1124
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	05-08-2005
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	NL57
NTR-old	NTR86
Ander register	ZON-MW : 3920.0005
ISRCTN	ISRCTN55332315

Resultaten

Samenvatting resultaten
N/A