

# Long-term outcome of pediatric major trauma

Published: 02-02-2007

Last updated: 09-05-2024

Aim of this study is to investigate the level of functioning and the quality of life of children and young adults, six to eight years after major trauma.

<b>Ethical review</b>	-
<b>Status</b>	Pending
<b>Health condition type</b>	Injuries NEC
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON30215

### Source

ToetsingOnline

### Brief title

Paediatric outcome

## Condition

- Injuries NEC

### Synonym

major trauma, multiple severe injuries

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht

**Source(s) of monetary or material Support:** Er worden collectebusfondsen aangeschreven

## Intervention

**Keyword:** Children, Functional health status, Major trauma, Quality of life

## Outcome measures

### Primary outcome

During their stay on the Emergency Department a lot of data is gained. Six to eight years after the initial trauma a number of questionnaires and scoring systems are fulfilled and physical examination is done. The questionnaires used to measure quality of life are the Pediatric Quality of Life Inventory (PedsQL 4.0) and the EuroQoL 6D (EQ 6D). The Vineland Adaptive Behavior Scales (VABS) and the Glasgow Outcome Scale (GOS) are used to measure the level of functioning on the ICF-domains *\*activity\** and *\*participation\**. The American Medical Association guides (AMA guides) are used to measure level of functioning on the ICF-domain *\*body function and structure\**. To measure *\*personal factors\** of the ICF-model the Child Behavior Checklist (CBCL) and the Pictorial Self-Evaluation Scale are used. For the measurement of *\*environmental factors\** of the ICF-model the Measure of Processes of Care (MPOC) and the Giving Youth a Voice Questionnaire (GYV-20) are used.

### Secondary outcome

none

## Study description

### Background summary

Injuries are the leading cause of death among children in the age-range of one to eighteen years old in the Netherlands. Injuries can cause severe functional

impairments en psychosocial problems, on short-term as well as long-term. Despite this prominent role of major trauma in the mortality and morbidity in children, only little investigation is done on the subject.

### **Study objective**

Aim of this study is to investigate the level of functioning and the quality of life of children and young adults, six to eight years after major trauma.

### **Study design**

Descriptive prospective cohort study

### **Study burden and risks**

Participants have to complete an amount of questionnaires and have to visit the clinic one time for physical examination. There is no risk associated with participation.

## **Contacts**

### **Public**

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### **Scientific**

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## **Trial sites**

### **Listed location countries**

Netherlands

## Eligibility criteria

### Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Adults (18-64 years)

Children (2-11 years)

Elderly (65 years and older)

### Inclusion criteria

All severely injured patients aged under 17 (Injury Severity Score >16), who were treated on the Emergency Department of UMCU in 1999 and 2000.

### Exclusion criteria

Patients transmitted to another hospital are excluded because of different treatment methods. Patients aged 17 or older are excluded, because they have already been evaluated in the study of H.R. Holtslag, with measures suitable for the adult population.

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

### Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-01-2007

Enrollment: 45

Type: Anticipated

## Ethics review

Not available

## 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
CCMO	NL15016.041.06