Prevalence, recovery patterns and risk factors of non-fatal outcome and costs after trauma; a prospective follow up study.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint injuries
Study type	Observational non invasive

Summary

ID

NL-OMON41989

Source
ToetsingOnline

Brief title
Non-fatal outcome after trauma

Condition

- Bone and joint injuries

Synonym
injury, trauma

Research involving
Human

Sponsors and support

Primary sponsor: Sint Elisabeth Ziekenhuis

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: costs, outcome, risk factors, trauma

Outcome measures

Primary outcome

The primary outcome parameters of this study are short and longterm HRQoL, functional and psychological outcome, and healthcare and societal costs in injured patients. Secondary outcome measures are Return to Work (RTW), and health care consumption.

We will measure socio-demographic characteristics, functional and psychological outcome and HRQoL shortly after trauma. Subsequently we will measure the same items after 1, 3, 6, 12 and 24 months. Health care consumption, costs and RTW will be measured at 1, 3, 6, 12 and 24 months after trauma.

Secondary outcome

Secondary outcome measures are Return to Work (RTW), and health care consumption.

Study description

Background summary

Intramural, extramural and societal costs can be high within the whole spectrum of trauma patients. Functional and psychological outcome can be negatively effected over years. Risk factors for a worse outcome can be diverse. Therefore we will conduct a prospective longitudinal study among all admitted trauma patients in the region Brabant independent of severity or classification of injury to evaluate the burden of injury from a patient and societal perspective.

Study objective

The major aim of this project is to investigate the prevalence, recovery patterns and risk factors for health related quality of life, functional, psychological, societal and economic outcome after trauma.
Another aim is to validate the World Health Organisation quality of Life (WHOQOL)-bref questionnaire for the trauma population.

Study design

This is a prospective, observational, follow-up study in which health related quality of life (HRQoL), psychological and functional outcome, and costs after trauma will be assessed during 24 months follow-up within injured patients admitted in one of the12 hospitals of Network Emergency Care Brabant. Patients with burns who will be initially seen on the Emergency Department of one of these 12 hospitals and who will be transferred to the Maasstad Hospital, will be asked to involve in the study as well. Inclusion period will be one year. To validate the WHOQOL-bref questionnaire will be included in 500 patients. In the Albert Schweitzer hospital 4 measure moments will take place during a period of 1-year. Patients and proxy's have to fill out measures digitally to determine quality of life.

Study burden and risks

The risks and inconvenience of participation are kept as low as possible. There are no medical interventions involved in the study as outcomes will be assessed using questionnaires. The time to complete the questionnaires will vary between 25 and 40 minutes. Patients are asked to fill in the questionnaires at six time points.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Patients seen at the ED which are admitted to the ICU or ward after getting injured.
• All types and severities of injury (ISS 1-75)
• A minimal age of 18 years old
• sufficient knowledge of the Dutch language

Exclusion criteria

• Patients who are dead on arrival or decease in the ED are excluded.
• Pathological fracture (i.e., the bones are weakened by disease, for example by a tumor).
• Patients who die in the hospital will drop out the study and will not be included in the analyses.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-08-2015
Enrollment:	8000
Type:	Actual

Ethics review

Approved WMO Date:	23-10-2014
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	17-12-2014
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	04-06-2015
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	25-06-2015
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	11-08-2015
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	17-09-2015
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	23-09-2015

Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	19-11-2015
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	18-01-2016
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	09-03-2016
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	10-05-2016
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	30-06-2016
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	13-09-2017
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL50258.028.14