Physical trauma patients with symptoms of an acute stress disorder: an observational study

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Primary objective: to examine the natural course of ASD symptoms Second objective: to determine the effects of ASD symptoms on the development of PTSD and patients* psychological distress (i.e., anxiety and depressive symptoms), coping, and QOL...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anxiety disorders and symptoms
Study type	Observational non invasive

Summary

ID

NL-OMON43971

Source
ToetsingOnline

Brief title
The course of acute stress disorder in physical trauma patients

Condition

- Anxiety disorders and symptoms

Synonym
Acute Stress Disorder

Research involving
Human

Sponsors and support

Primary sponsor: Sint Elisabeth Ziekenhuis
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Acute Stress Disorder, Course, Physical trauma, Post Traumatic Stress Disorder

Outcome measures

Primary outcome

The first outcome measures are incidence of ASD and PTSD, and anxiety at one

year after treatment for physical trauma.

Secondary outcome

The secondary outcome measures are psychological distress, coping, and QOL.

Other study parameters are personality and trait anxiety, medical history (e.g.

previously treated in shock room due to physical trauma), and history of

psychological and/or psychiatric disorders.

Study description

Background summary

Type-I-trauma (single traumatic event) can cause severe symptoms of PTSD. Within the physical trauma injury literature, studies have shown that 43-84% of the patients experience psychosocial problems, including PTSD, after trauma. These problems are related to increased pain, opioid use, and reduced quality of life (QOL). In patients with physical trauma patients ASD has hardly been studied.

Study objective

Primary objective: to examine the natural course of ASD symptoms
Second objective: to determine the effects of ASD symptoms on the development of PTSD and patients* psychological distress (i.e., anxiety and depressive symptoms), coping, and QOL across time.
Third objective: to identify subgroup(s) of patients in whom ASD symptoms remain or increase. This provides valuable insight in the need for a

psychological intervention to prevent PTSD.

Study design

This is a prospective cohort study

The incidence of ASD and PTSD, psychological distress (i.e. anxiety and depression), coping and QOL will be assessed up to one year after treatment for physical trauma. All outcome measures will be assessed at baseline (i.e., after treatment in shock room), 3, 6, 9 and 12 months after treatment for physical trauma. Personality and trait anxiety will only be measured at baseline.

Study burden and risks

This project is exploratory in nature. Therefore, the risks and discomforts of participation are kept as low as possible. By determining the course of ASD symptoms and identifying patients who are at risk, medical caregivers are able to act more effective so that patient-oriented care can be given. Outcomes will only be assessed using questionnaires. The time to complete the self-reported questionnaires will be approximately 30-45 minutes. Patients are asked to fill in questionnaires at six time points of which the first one is during admission after trauma.

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

Being treated in the shock room, being aged 18 or older

Exclusion criteria

Severe neurology trauma (i.e. severe traumatic brain injury (TBI)), dementia, age below 18 years, and insufficient knowledge of the Dutch language (verbal and in writing).

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-03-2016
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	04-12-2015
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	21-11-2016
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	08-11-2017
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	NL55386.028.15

Study results

Results posted: 28-01-2021

First publication
02-05-2018