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Predicting effects of severe trauma on health, disability and quality of life

Submission date
30/04/2018

Recruitment status
No longer recruiting

Registration date
11/05/2018

Overall study status
Completed

Last Edited
04/06/2019

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
Physical trauma is a healthcare problem all over the world and the main cause of death in young adults. Portugal is the leader among European countries concerning death related to accidents. The real dimension of the problem is not well known in Portugal as not enough studies have been performed on this subject. Therefore, our first and main objective is to know more about the frequency and types of physical trauma in Portugal as well as about its severity and consequences in terms of death and disease. Data from a Portuguese registry may help to understand this.
Death is the worst consequence of trauma but is not the only problem for those injured people. As technology improves, more people who suffer serious injuries during an accident can survive. And even the milder forms of trauma can result in significant problems that may affect people for a long time or might start after the injury.
From what we know, people who suffer some type of accident are often young and otherwise healthy. Many different types of physical disabilities can persist after the accident, as well as thought, behaviour or mood disturbances. All these problems can significantly affect patients, both in their immediate well-being, as well as by creating long-standing limits to their ability to live normally. Patients may appear physically recovered, but problems reintegrating into family, work, or school can appear. These can worsen quality of life. People who have had a traumatic injury should receive education on how they might feel about the injury and should be referred for physiotherapy or psychological treatment as soon as possible. People often receive excellent care for their injury in hospital, but don't get followed up once they are home. Many of these patients can achieve good recovery and reintegration into family and work life, but will require continuous and possibly life-long access to many different doctors. This means that their quality of life is a good as possible and is cost-effective in the long run. This process should start at the first contact with the patient and family. It should involve close collaboration between the family, patient, emergency physician, intensive care specialist, surgeons, psychiatrists, rehabilitation medicine and other therapists, rehabilitation facilities, the workplace and community groups.
This study had three aims:
1. To discover consequences of severe trauma in terms of death, development of disease and psychological limitations, disabilities and quality of life.
2. To determine whether there is a relationship between the initial accident and its treatment

and the development of trauma-related disease.
3. To develop a way to predict quality of life after severe trauma.
The follow-up consultation developed for this project did an interview at 6 months after trauma. The main objectives were to ask for and diagnose problems in the patient as well as to serve as a base for data collection and research on late problems that can arise after trauma. Several questions and physical investigations were done to find out which problems are important at 6 months after the accident. We therefore asked patients to reply to some questionnaires, which include Mini Mental State; Glasgow Outcome Scale and Glasgow Outcome Scale Extended and EQ-5D).

Who can participate?
People who had a severe injury that required surgery to blood vessels, chest, brain or spinal cord.

What does the study involve?
The patients were interviewed 6 months after the injury. The main objectives were to ask for and diagnose problems in the patient as well as to serve as a base for data collection and research on late problems that can arise after trauma. Several questions and physical investigations were done to find out which problems were important at 6 months after the accident. Patients also filled in questionnaires, which included Mini Mental State; Glasgow Outcome Scale and Glasgow Outcome Scale Extended and EQ-5D.

What are the possible benefits and risks of participating?
There were no benefits or risks of participating.

Where is the study run from?
Hospital de Santo António, Porto, Portugal

When is the study starting and how long is it expected to run for?
January 2013 to December 2013.

Who is funding the study?
Fundação para a Ciência e a Tecnologia [Portuguese Science and Technology Foundation]

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PIC/IC/83120/2007

Study information

Scientific Title
Outcome after severe trauma: Implications for the clinical approach

Study objectives
1. To evaluate the consequences of severe trauma in terms of mortality, functional and psychological impairments, disabilities and quality of life
2. To determine whether a relationship between the initial event - namely epidemiological aspects, injury severity, types of injury and analytical, clinical markers of severity and presence or absence of the “Golden Hour” approach - and the outcome exists.
3. To discuss the “trimodal mortality” and the “Golden Hour” concepts and its implications in a Portuguese modern trauma system from the clinical and also organizational point of view.
4. Development of informatic systems and tools to support the registry as well as share and validation of data. This includes creating a predictive score called Global Outcome After Trauma (GOAT) to identify patients who may have worse outcomes after severe trauma.
5. To analyse the relationship between disability, cognitive impairment and health-related quality of life (HRQoL) in adult patients after trauma with and without traumatic brain injury (TBI).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Committee for Ethical Research at the Hospital de Santo António, Porto, Portugal, 26/03/2006, 08/CES/06

Study design
Cross-sectional observational study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)

Screening

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Mortality, functional and psychological impairments, disabilities and quality of life in severe trauma patients

Interventions
We analysed prospectively collected data from a trauma database that included all trauma patients admitted to the Emergency Room of Hospital de Santo António (HGSA) for a period of 5 years. HGSA is a 700-bed tertiary hospital, equivalent to an American College of Surgeons classification of a level 1 trauma centre and serves an area of 2.5 million people.
For the purpose of this study we examined all severe trauma patients (ISS >15) registered between January 2003 and December 2007 and who were alive 6 months after the injury. Our institutional review board approved the study and informed consent was obtained from patients. We performed a follow-up consultation that consisted of a structured interview and several self-administered tests. Data concerning disability, cognitive impairment and HRQoL was gathered and analysed.

Intervention Type
Other

Primary outcome measure
1. Disability was assessed by the Glasgow Outcome Scale Extended (GOSE)
2. Cognitive impairment was assessed by the Mini Mental State (MMS) test
3. HRQoL was assessed with a modified EuroQol 5-Dimensions (EQ-5D-3L) questionnaire.

Secondary outcome measures
N/A

Overall study start date
01/01/2003

Completion date
31/12/2013

Eligibility

Key inclusion criteria
Need for specialized trauma care (vascular surgery, neurosurgery or thoracic surgery) and/or severe trauma (defined by an ISS >15).

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
600

Total final enrolment
262

Key exclusion criteria
1. Aged <13 years
2. Diagnosis of poisoning or overdose
3. Diagnosis of drowning or suffocation
4. Burns
5. Iatrogenic accidents
6. Isolated hip fractures in patients aged >65 years

Date of first enrolment
01/01/2003

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
Portugal

Study participating centre
Hospital Geral de Santo Antonio, Centro Hospitalar do Porto
Largo Professor Abel Salazar, 4099-001 Porto, Portugal
Porto
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Sponsor information

Organisation
Fundacao para a Ciencia e Tecnologia

Sponsor details
Av. D. Carlos I, 126, 1249-074 Lisbon
Lisbon
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1249-074

Sponsor type
Government

Website
https://www.fct.pt

ROR
https://ror.org/00snfqn58

Funder(s)

Funder type
Not defined

Funder Name
Fundação para a Ciência e a Tecnologia

Alternative Name(s)
Foundation for Science and Technology, Portuguese Science and Technology Foundation, Fundacao para a Ciencia e a Tecnologia, FCT

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Portugal

Results and Publications

Publication and dissemination plan
Results to be published in Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2019	04/06/2019	Yes	No