Pilot study: Epidemiology, quality of life and costs of burn injuries presenting to emergency departments in a Dutch trauma region

Published: 18-11-2013
Last updated: 24-04-2024

The primary objective of this study is: To evaluate and improve patient recruitment procedures and follow-up methods. The secondary objectives are: (1) To determine the response rate before and after the introduction of optimized patient recruitment...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON38973

Source
ToetsingOnline

Brief title
Epidemiology, Qol and costs of burns at ED

Condition

- Other condition

Synonym
burn wounds, Burns

Health condition

Brandwonden

Research involving

Human

Sponsors and support

Primary sponsor: Maasziekenhuis
Source(s) of monetary or material Support: Het onderzoek wordt gefinancierd door de Nederlandse Brandwonden Stichting en de Vereniging Samenwerkende Brandwonden Centra Nederland.

Intervention

Keyword: Burns, Costs, Emergency department, Methodology

Outcome measures

Primary outcome

The main study parameter will be the response rate in the patient group contacted using the normal recruitment strategy and in the patient group contacted using the optimized recruitment strategy. Response rates will be calculated for both the total groups and for subgroups of patients, as far as possible.

Secondary outcome

Secundary paramters are:

- Data on socio demographic (age, gender, education, ethnicity) and burn characteristics (etiology, setting (home, work, else), firework (yes/no), body region, extent of the burn), and comorbidity

- Both generic and burn specific quality of life

- Data on post-traumatic stress symptoms will be assessed using the Impact of Event Scale

- Data on patients extramural medical costs and indirect costs (productivity loss, absenteeism) will be collected 2 and 6 months post injury, using a

questionnaire *Costs and medical consumption*

Study description

Background summary

Rationale: Data on epidemiology, outcomes and costs of burn injuries presenting at emergency department (ED)s are scarce. Dutch data on the epidemiology of burn injures presenting at EDs can be derived from the Injury Surveillance System (LIS), but provide limited information, and generalizability is not established for patients with burns. Furthermore, to our knowledge, no studies exist into the quality of life (QOL) after burns treated at an ED and data on medical or societal costs after burns treated at an ED are scarce. No studies exist which incorporate all three study domains.
In previous studies conducted on quality of life (QOL) after specialized burn care in both pediatric and adult populations and QOL after injury in general presenting at an ED, questionnaires proved to be feasible, however, response rates were low (37-43%). In studies using (postal) questionnaires, the response rate is crucial for the efficiency of the study. A low response rate will require to address more patients and could even result in an insufficient sample size. In this pilot study, emphasis will be put on the evaluation and optimization of patient recruitment procedures and follow-up methods. By optimizing the recruitment strategy and to compare this strategy to the standard recruitment strategy we aim to demonstrate an increase in response of patients. In addition, it is unclear whether specific high risk groups of burn patients, for instance patents with lower socio-economic status are present in the selected study region, and if so whether response rates differ between high risk groups, for burn injuries. As a next step, we aim to conduct a larger study to evaluate the epidemiology, quality of life and costs of burn injuries presenting at all EDs within Network Emergency Care Brabant (NAZB, formerly known as Trauma Centre Brabant), using the knowledge from this pilot study.

Study objective

The primary objective of this study is: To evaluate and improve patient recruitment procedures and follow-up methods. The secondary objectives are: (1) To determine the response rate before and after the introduction of optimized patient recruitment procedures and follow-up, (2) To examine to what extent high risk groups are represented among patients with burn-related injuries attending to one of the two EDs and among the group of respondents, (3) To obtain first insights into the epidemiology, quality of life and costs of burn injuries presenting at EDs.

Study design

In a prospective follow-up study, all patients with burn-related injuries attending two larger EDs from trauma region Brabant during 3 months will be included. The follow-up period will be 6 months as patients will receive questionnaires after 2 and 6 months after the first ED visit. Patients attending the ED in the first month will be approached using the standard recruitment strategy and patients attending the ED in the other months will be approached using the optimized recruitment strategy. The EDs at Amphia hospital (Breda) and St. Elisabeth hospital (Tilburg) will participate in this study.

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 depends on the age group and time of assessments, and will vary between 15 min (assessment after 2 months) and 25 minutes (assessment after 6 months). Moreover, special questionnaires will be given to minors and data on post-traumatic stress symptoms will only be assessed in adults using the Impact of Event Scale.

Contacts

Public
Maasziekenhuis

Maasstadweg 21
Rotterdam 3079 DZ
NL
Scientific
Maasziekenhuis

Maasstadweg 21
Rotterdam 3079 DZ
NL

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 patients with burn-related injuries attending one of the two EDs from the trauma region Brabant between 1st of November 2013 and 1st of February 2014 (3 months).

Exclusion criteria

Patients who provide incomplete contact information will be excluded from the study.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-01-2014
Enrollment:	132
Type:	Actual

Ethics review

Approved WMO Date:	18-11-2013
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	16-12-2013
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	NL46438.008.13