Epidemiology, treatment (costs) and long-term outcomes of patients with fireworks-related injuries (ROCKET); a multicenter prospective observational case series

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26638

Source
Nationaal Trial Register

Brief title
ROCKET

Health condition

Fireworks-related injuries

Sponsors and support

Primary sponsor: Erasmus MC, University Medical Center Rotterdam, Trauma Research Unit, Department of Surgery
Erasmus Medical Center, Medical Research Ethics Committee (MREC)
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Fireworks-related injury characteristics

Secondary outcome

- Number and type of operations

- Duration of hospital admission

- Direct medical and indirect societal costs

- Absence from school

- Quality of life (EuroQol-5D-3L; EQ-5D-3L)

- Health Utilities Index 3; HUI-3 (domains vision and dexterity)

- Visual acuity

- Quick Disabilities of Arm, Shoulder and Hand (Quick-DASH)

- Cold Intolerance Severity Scale (CISS)

- Lower Extremity Functional Scale (LEFS)

- Patient and Observer Scar Assessment Scale (POSAS)

- Patient satisfaction with their functional recovery and cosmesis

- How trauma has affected patient¡¯s view on the use of consumer fireworks

Study description

Background summary

BACKGROUND

Fireworks-related injuries frequently occur in both adults and children. It often entails serious and avoidable injuries to innocent bystanders. Most injuries are non-fatal but a substantial amount results in life-long disabilities affecting quality of life and the use of public health services. Currently, reliable data about the affected patients, their injury characteristics, the

direct and indirect costs resulting from their injury and the loss of quality of life outcomes in the long-term is lacking.

AIM

The primary aim of this study is to determine the injury characteristics of fireworks-related injuries in patients reporting to a hospital for treatment.

The secondary aims are:

1) To determine the number and type of operations needed due to of fireworks-related injuries until one year after trauma

2) To determine the duration of hospital admission in these patients

3) To determine the direct medical costs and the indirect societal costs (incl. work absence) in these patients

4) To investigate the absence from school in these patients

5) To investigate the patient-reported outcomes in these patients

- EuroQol-5D (EQ-5D-3L)

- Health Utility Index Mark 3 (domains for vision and dexterity) (HUI-3)

- Quick Disabilities of the Arm, Shoulder and Hand (Quick-DASH)

- Cold Intolerance Symptoms Severity (CISS)

- Lower Extremity Functional Scale (LEFS)

- Patient and Observer Scar Assessment Scale (POSAS)

- Patient satisfaction with the functional recovery and cosmesis

6) To investigate how the injury changed patient¡¯s view on the use of fireworks

STUDY DESIGN

Multicenter, prospective, observational study (case series)

POPULATION

All patients (no age limit) with fireworks-related injuries presenting to a hospital in the period between December 1, 2017 and January 31, 2018 in the Trauma Region Southwest Netherlands.

INTERVENTION

Not applicable.

ENDPOINTS

Primary outcome measure: fireworks-related injury characteristics.

Secondary outcome measures: Number and type of operations; Duration of hospital admission; Direct medical and indirect societal costs; Absence from school; Quality of life (EuroQol-5D-3L; EQ-5D-3L); Health Utilities Index 3; HUI-3 (domains vision and dexterity); Visual acuity; Quick Disabilities of Arm, Shoulder and Hand (Quick-DASH); Cold Intolerance Severity Scale (CISS); Lower Extremity Functional Scale (LEFS); Patient and Observer Scar Assessment Scale (POSAS); Patient satisfaction with their functional recovery and cosmesis; How trauma has affected patient¡¯s view on the use of consumer fireworks.

RECRUITING COUNTRIES

The Netherlands.

Study objective

Fireworks-related injuries have a substantial impact on the medical costs, but a much larger impact on the societal costs.

Study design

2 weeks, 3 months, 6 months, and 12 months after hospital presentation.

Intervention

Not applicable

Contacts

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Eligibility criteria

Inclusion criteria

1) Patients with any injury caused by fireworks treated* in a hospital in the Trauma Region Southwest Netherlands between December 1, 2017 and January 31, 2018

2) Provision of informed consent

* Treatment is defined as any intervention for which ¡Ý1 clinical follow-up visit is scheduled

Exclusion criteria

1) Patients who died within the first 24 hours due to other injuries than fireworks

2) Patients with incomplete or unknown contact information;

3) Insufficient understanding of Dutch or English to understand the study documents

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2017
Enrollment:	75
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	31-10-2017
Application type:	First submission

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
NTR-new	NL6608
NTR-old	NTR6793
Other	METC Erasmus MC : MEC-2017-1066 (METC Erasmus MC)

Study results

Summary results

Van Yperen DT, Van der Vlies CH, De Faber JTHN, Penders CJM, Smit X, Van Lieshout EMM, Verhofstad MHJ, ROCKET-Studiegroep .
[Firework injuries in the south-western region of the Netherlands around the turn of the year 2017-2018].
Ned Tijdschr Geneeskd. 2018 Nov 29;162