

Burden of burn injuries: quantifying the societal impact of burns with a state-of-art burden of disease methodology

No registrations found.

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

Summary

ID

NL-OMON25544

Source

Nationaal Trial Register

Brief title

BOD study

Health condition

Long-term consequences of burns

Sponsors and support

Primary sponsor: Prof. dr. E. Middelkoop

Association of Dutch Burn Centres (ADBC)

P.O. Box 1015

1940 EA Beverwijk

Source(s) of monetary or material Support: Dutch Burn Foundation

Grant number: 15.102

Intervention

Outcome measures

Primary outcome

Long-term generic HRQL of children and adult burn survivors will be assessed by the 'EuroQol-5D-5L + cognitive domain' (EQ-5D-5L).

Secondary outcome

The secondary outcome parameters of this study are long-term burn specific HRQL, long-term functions, activities and participation of burn survivors:

☐ Burn specific HRQL

- o Score on the Burns Specific Health Scale-brief (BSHS-B) in adults

- o Score on the Burn Outcome Questionnaire (BOQ) in children aged 5 – 18 years

☐ Scar quality

- o Score on the Patient and Observer Scar Assessment Scale (POSAS) patient score

☐ Itching of scar

- o Score on the POSAS patient score

☐ Depressive symptoms

- o Score on the Beck Depression Inventory (BDI-II-NL)

☐ Perceived stigmatization

- o Score on the Perceived Stigmatization Questionnaire (PSQ) in adults

☐ Participation

- o Score on the Work Productivity and Activity Impairment General Health (WPAI-GH)

Additional parameters, only for the cohort on extensive burns:

☐ Scar quality

- o Score on the POSAS observer score

☐ Contractures

- o Reconstructive surgery

☐ Muscular strength

- o Grip strength (Force in Newton) measured by a Hand-Held Dynamometer

- Aerobic capacity
 - o Maximum achieved wattage during the Steep Ramp Test (SRT)
- Habitual physical activity patterns
 - o Score on the Habitual Physical Activity Questionnaire (PAQ)
- Fatigue
 - o Score on the Brief Fatigue Inventory (BFI)
- Body composition
 - o Body mass index (BMI) and waist circumference

Study description

Background summary

SUMMARY

Rationale: Burden of disease calculations are an important resource in public health. The burden of disease aggregates all health consequences of a disease in one metric and is increasingly used for priority setting in health care, surveillance and interventions. For the calculation of the burden of disease, information on long-term consequences of the specific disease is needed. Currently, little is known about the long-term consequences and secondary conditions after burns. Therefore, calculation of the burden of burns is challenging.

Objective: To obtain a comprehensive overview of long-term (≥ 5 years after burn injury) consequences after burn injuries, both in all patients admitted to burn centre admissions and in a subgroup of patients who suffered from more extensive burns.

Study design: A multicentre cross-sectional study.

Study population: All burn patients (children and adults) who have been admitted to one of the three Dutch burn centres in the period August 2011 – July 2013 and with a hospital stay of more than one day or who have had surgical treatment for their burns.

For the cohort on extensive burns: all patients with extensive burns (over 20% total body surface area (TBSA)) in adults, over 10% TBSA in children < 10 years or adults > 50 years or TBSA third degree $> 5\%$ who had an admission to one of the three Dutch burn centres in the period 2010 – 2013.

Intervention (if applicable): Not applicable

Main study parameters/endpoints: To assess long-term health-related quality of life and long-term functioning, activities and participation of burn survivors, questionnaires that include questions on health-related quality of life, on body functioning, on participation and on environmental factors will be assessed in all patients.

In addition, to fully elucidate long-term consequences of extensive burns, muscular strength, aerobic capacity, contractures, body composition, fatigue, and habitual physical activity will be assessed in patients with extensive burns.

Study objective

An observational study to obtain a comprehensive overview of long-term (≥ 5 years after burn injury) consequences after burn injuries, both in all patients admitted to burn centre admissions and in a subgroup of patients who suffered from more extensive burns.

Study design

Outcomes will be assessed once. At least 5 years after burns.

Intervention

None

Contacts

Public

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Scientific

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Eligibility criteria

Inclusion criteria

- Patients of all ages with a hospital stay of ≥ 1 night or with surgical treatment for their burns in the period August 2011 – July 2012

- Informed consent

For the extended cohort on severe burns:

- Patients (≥ 10 - ≤ 50 years old) with major burns (over 20% TBSA)

- Patients (< 10 and > 50 years old) with major burns (over 10% TBSA)

- Patients with TBSA third degree $> 5\%$

Exclusion criteria

Insufficient knowledge of the Dutch language

Deceased

Study design

Design

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

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-03-2017
Enrollment:	448
Type:	Anticipated

Ethics review

Positive opinion

Date: 16-02-2017

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 43284

Bron: ToetsingOnline

Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6249
NTR-old	NTR6407
CCMO	NL59981.101.16
OMON	NL-OMON43284

Study results