Evolution of physical activity and fitness in children and adolescents after burn injury

Published: 18-11-2013
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Investigate how physical fitness and activity evolve over time in paediatric burn patients, also in relation to function.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Musculoskeletal and connective tissue disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON38885

Source
ToetsingOnline

Brief title
Evolution of physical activity and fitness in children after burn injury

Condition

- Musculoskeletal and connective tissue disorders NEC
- Skin and subcutaneous tissue disorders NEC
- Lifestyle issues

Synonym
burns; burn injury

Research involving
Human

Sponsors and support

Primary sponsor: Martini Ziekenhuis
Source(s) of monetary or material Support: Nederlandse Brandwonden Stichting

Intervention

Keyword: activity, burns, children, fitness

Outcome measures

Primary outcome

Change in physical fitness, specifically aerobic capacity expressed as WRpeak

(WRpeak) and VO2peak (ml/min), also relative for weight (ml/kg/min)) over time,

from hospital discharge to 6 months post discharge.

Secondary outcome

Change from hospital discharge to 6 months post discharge in:

• Physical fitness

* Aerobic capacity

- Peak heart rate (HRpeak; beats per minute)

- Percentage heart rate recovery after 1 and 2 minutes (%HR01 and %HR02)

* Muscular strength

- Force (Newton) per muscle group

* Flexibility

- Range of motion (degrees) per movement

* Body composition

- BMI (kg/m2)

- Waist circumference (m)

- Percentage fat (free) mass

• Physical activity

- Score on activity questionnaire *Beweeggedrag*

- Accelerometry (counts)

• Health-Related Quality of life

- Score on the Burn Outcome Questionnaire

- Score on the PedsQL Multidimensional Fatigue Scale

To establish how well children are doing, the above parameters (main and secondary) will be compared to Dutch age and sex-matched reference values.

Furthermore, the study parameters will be adjusted for confounders.

Study description

Background summary

With the marked improvement of survival of patients with burns, the ultimate goal of rehabilitation is to assist individuals in returning to their pre-injury functional status, while maximizing their emotional and cosmetic outcomes. People survive burn injuries after an often extensive period of physiological assault, decreased physical activity and an increased demand of proteins leading to catabolism, especially of muscle mass. Loss of physical fitness as a consequence of burn injury therefore seems inevitable. Indeed, physical fitness has been found to be affected after burn injury and exercise training can effectively improve physical fitness. However, knowledge is incomplete, only pertaining to a small, specific group of patients, i.e. children with very severe burns. If we are to optimise rehabilitation programs to help children timely achieve their maximal, if not pre-injury, functional status, after burn injury, we need to know how their fitness and activity evolve and how this is related to their functioning.

Study objective

Investigate how physical fitness and activity evolve over time in paediatric burn patients, also in relation to function.

Study design

Prospective observational longitudinal study

Study burden and risks

The risks and inconvenience of participation are kept as low as possible. The physical fitness assessments are performed four times. As an important component of physical fitness, aerobic capacity will be assessed with an exercise test on a cycle ergometer. In stead of performing the usual exhaustive cardiopulmonary exercise test, the Steep Ramp Test will be used. An important difference between the SRT and usual cardiopulmonary exercise test is its duration: the SRT takes between 2 and 3 min. excluding warm-up and cooling down. The SRT is very well accepted by children, also if not healthy. The risks for exercise tests are minimal. Additionally, before testing, a physician has checked the health status of each participant and they are screened by way of the Exercise Pre-participation Screening form. In case of contra-indications a physician will be consulted and a child may be excluded from the exercise test. During the exercise test, the heart rate will be supervised. The test will be stopped in case of abnormal values. The other fitness assessments (muscular strength, body composition, and flexibility) are safe and non-intensive. The physical fitness assessments will take approximately 1 hour each time and they will be scheduled in combination with routine follow-up appointments. Physical activity monitoring with an accelerometer is without risk and the inconvenience of wearing the accelerometer is low, as it is a very small and low-weight device, worn as a waistband. Filling out the questionnaires will take approximately 30 minutes each time, but can be done during one week at the patients* and/or parents* convenience. In summary, risks are negligible and the burden of participation seems minimal.

This study is only possible by including this specific paediatric population, as burns have very specific, multidimensional consequences and children*s physiological and psychological response differs from adults*. The group benefit mainly is improvement in the domain of individualized rehabilitation and with that better physical functional outcomes for paediatric burn patients in the (near) future. Children can benefit individually by becoming aware of their own fitness and activity levels and their importance.

Contacts

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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

Eligible are children in the age between 6 and 18 years, who are admitted to one of the three Dutch Burn Centres with burns of at least 5% total body surface area or more and/or hospitalised for 2 weeks or more.

Exclusion criteria

- patients with extensive (pre-existing) morbidity unrelated to the burn injury, interfering with fitness
- children and/or their parents who are insufficiently proficient in Dutch
- no signed informed consent (by legal representatives (parents) and/or children if > 12 years)
* children with a contra-indication for exercise testing will not perform the cycling test, however, may otherwise be included.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-05-2014
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	18-11-2013
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

Approved WMO

Date:	02-06-2014
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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	NL45917.099.13
Other	OND1353942