Long-term physical activity and fitness after pediatric burns

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Investigate the long-term recovery of physical activity and physical fitness following pediatric burns, and link the results of former participants to their scores obtained during the initial six months.

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

Summary

ID

NL-OMON48389

Source
ToetsingOnline

Brief title
Long-term physical activity and fitness after pediatric burns

Condition

- Other condition
- Musculoskeletal and connective tissue disorders NEC
- Skin and subcutaneous tissue disorders NEC

Synonym
burn injury, burns

Health condition

brandwonden

Research involving
Human

Sponsors and support

Primary sponsor: Martini Ziekenhuis
Source(s) of monetary or material Support: De drie Nederlandse Brandwondencentra (in kind)

Intervention

Keyword: activity, burns, children, fitness

Outcome measures

Primary outcome

Exercise capacity (expressed as peak power output (POpeak) and POpeak divided

by body weight (POpeak/kg)) 5 years after discharge.

Secondary outcome

5 years after discharge:

* Physical fitness

* Grip strength

- Force (kg)

* Flexibility

- Range of motion (degrees) of major joints

* Body composition

- BMI (kg/m2)

- Waist circumference (cm)

* Physical activity

- Score on activity questionnaire *Beweeggedrag*

- Accelerometry (counts, daily time spent in various activity

intensities)

* 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 will be compared to Dutch age and sex-matched reference values. Furthermore, the study parameters will be adjusted for confounders.

Study description

Background summary

Due to the pathophysiology of burns and the long periods of hospital stay, loss of physical fitness after pediatric burn injury seems inevitable. Recovery of physical fitness is an important prerequisite for the return to home, school and age-specific activities. However, whereas achieving adequate levels of physical activity and fitness is important on the short term, there is also a growing understanding of the importance of maintaining certain levels of physical activity and fitness throughout life to prevent disability and morbidity later on in life. The first results of our longitudinal prospective cohort study (RTPO 901), examining the course of physical activity and fitness following pediatric burns during the initial six months after discharge, showed that half of the children and adolescents with moderate to major burns did not achieve healthy reference values of exercise capacity within six months. Some of them did not even show improvement over time (Akkerman et al, submitted). Furthermore, the majority of participants with burns across or adjacent to a major joint (12/16) still had scar contractures limiting function six months after discharge (Oosterwijk et al, submitted). These results emphasize the importance of paying attention to their long term recovery. For this reason, we aim to assess physical activity and fitness in all patients that were eligible at the time of our former study (RTPO 901) five years after discharge.

Study objective

Investigate the long-term recovery of physical activity and physical fitness following pediatric burns, and link the results of former participants to their scores obtained during the initial six months.

Study design

Cross-sectional assessment in addition to a former longitudinal prospective cohort study (RTPO 901)

Study burden and risks

The risks and inconvenience of participation are kept as low as possible. All physical fitness assessments are performed once. As an important component of physical fitness, exercise 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. Before testing, each participant is screened by way of an Exercise Pre-participation Screening form. In case of contra-indications, a physician will be consulted and the participant 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 and patterns. The other fitness assessments (muscular strength, body composition, and flexibility) are safe and non-intensive. The physical fitness assessments will take approximately 45 minutes and they will be scheduled in consultation with the participant, if possible in combination with a routine follow-up appointment.
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, and can be done during one week at the patients* and/or parents* convenience.
In summary, risks are negligible and the burden of participation is minimal.

We will only ask the patients who were eligible at the time of our longitudinal prospective cohort study (RTPO 901, n=53). This cohort allows us to assess whether differences exist with regard to physical activity and fitness between those who did participate in our former study and those who did not. Furthermore, having previous data from our former participants makes it possible to link these long term follow-up results to their scores during the initial six months after discharge, and further examine the predictive value of early physical assessment.

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 and their parents can benefit individually by gaining insight in their current level of physical fitness and being informed about the importance of a healthy active lifestyle, especially following pediatric burns.

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, adolescents, and young adults who were eligble for the ePAF study from March 2014 to February 2017. These patients were between 6 and 18 years when they were admitted to one of the three Dutch burn centres with (1) burns affecting 5% of total body surface area or more or (2) a length of hospital stay of two weeks or more, or both.

Exclusion criteria

- extensive morbidity unrelated to the burn injury, interfering with physical fitness
- insufficient proficiency in Dutch (children and/or their parents) to the extent that clear communication is not possible
- no signed informed consent (by the parents and/or children 12 years and older)
* patients with a contra-indication for exercse 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):	16-03-2020
Enrollment:	53
Type:	Actual

Ethics review

Approved WMO

Date:	27-06-2019
Application type:	First submission
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	NL69376.099.19
Other	OND1365887