Growth and Development in Children after Burns; a Multi-Centre Prospective Cohort Study

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To investigate the short-term and long-term effects of burn injuries on growth and development of paediatric patients of all ages relative to the size and degree of the burn injury.

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

Summary

ID

NL-OMON49548

Source
ToetsingOnline

Brief title
Growth and Development in Children after Burns (GOPS)

Condition

- Other condition
- Skin and subcutaneous tissue disorders NEC
- Skin and subcutaneous tissue therapeutic procedures

Synonym
Burn injuries, burns

Health condition

Brandwonden

Research involving

Human

Sponsors and support

Primary sponsor: Rode Kruis Ziekenhuis
Source(s) of monetary or material Support: De Nederlandse Brandwondenstichting

Intervention

Keyword: Burns, Children, Development, Growth

Outcome measures

Primary outcome

The primary study parameter is the deviation from the predicted weight curve at

twelve months post-burn (Z-scores).

Secondary outcome

Secondary endpoints include other post-burn growth and development outcomes

compared to both predicted and Dutch reference values.

Study description

Background summary

Over the past few decades, a paradigm shift has occurred in burn care towards improving survivorship which entails identifying and treating the physical and psychological impact of burns. Improving quality of life means striving for scar free healing, but also includes helping patients to achieve their maximal (pre-burn) health status. Young children and adolescents are a large subgroup (40%) of the entire burn patient population. Paediatric patients are a particularly vulnerable group for whom the burden of post-injury morbidity may be experienced during the remainder of their lifetime. The nature and severity of the body*s hypermetabolic response to burns may plausibly give rise to developmental, growth and scar growth problems in these young patients. Knowledge on these topics is incomplete and only pertained to a rare subgroup of patients with extensive burns (>40% of the total body surface area).

Study objective

To investigate the short-term and long-term effects of burn injuries on growth and development of paediatric patients of all ages relative to the size and degree of the burn injury.

Study design

Multi-centre prospective cohort study.

Study burden and risks

Having been discharged from the hospital, the patient is still in need of follow-up care. To limit the burden on the patient and to prevent repeated measurement of common data, data collection and follow-up visits for the study will take place simultaneously with the regular follow-up visits, which take place in the outpatient clinic, at one week and three, six, twelve, and twenty-four months post discharge. During each visit, a selection of the following measurements will be completed (see: 2. STUDY DESIGN, page 12): length, weight, waist circumference, handgrip strength, scar surface area, and scar quality. Preceding the visit, the patient*s parents or legal representatives are asked to fill in three brief questionnaires in an e-health platform designed for regular follow-up care. The extra time needed for the study measurements is limited to 15-20 minutes per visit. Also, the measurements are neither hazardous nor invasive, making the burden and risk associated with study participation negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

1) The patient is <18 years old, at the time of the burn injury.
2) The patient has a burn injury that requires surgical treatment or admission of 24 hours or more, at one of the three Dutch burn centres (Rode Kruis Ziekenhuis, Maasstad Ziekenhuis, Martini Ziekenhuis).

Exclusion criteria

1) Patients with electrical burns will be excluded, as the nature and physiology of electrical burns differs from other burn injuries.
2) Patients, parents, and caretakers with insufficient Dutch language skills, or otherwise incapable of providing informed consent.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting

Start date (anticipated):	18-11-2020
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO Date:	11-09-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL73435.029.20
Other	OND1368144