

A multicenter study on pain measurement among children with burns: assessment of reliability and validity of the POCIS and COMFORT scale

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

Summary

ID

NL-OMON30015

Source

ToetsingOnline

Brief title

Pain measurement in children with burns

Condition

- Other condition
- Epidermal and dermal conditions

Synonym

pain assessment, pain measurement

Health condition

pijn

Research involving

Human

Sponsors and support

Primary sponsor: Vereniging Samenwerkende Brandwondencentra Nederland

Source(s) of monetary or material Support: nederlandse brandwonden stichting

Intervention

Keyword: burns, Comfort scale, pain, Pocis

Outcome measures

Primary outcome

1. What is the reliability of Pocis en Comfort scale?
2. What is the validity of Pocis en Comfort scale?
3. What is the use-friendliness of both scales indicated by nurses?

Secondary outcome

None

Study description

Background summary

Burns are extremely painful. Pain is categorized into two categories: background pain (pain at rest) and procedural pain (pain caused during manipulation of wounded body parts). Children aged 0 to 4 years are not or insufficiently capable of verbal indicating pain. For that reason, the literature suggests the use of pain observation scales in order to assess pain in this group of young children.

In the Netherlands there is no pain scale available that has been tested to assess pain in children with burns. Pocis and Comfort scales were used to assess post operative pain, which cannot be generalized to measure procedural pain in children with burns. For that reason, it is necessary to examine pain in the clinical setting in this specific group of children.

Study objective

To assess validity and reliability of two pain observation scales in children with burns aged 0 to 4 years. Moreover, nurses will be asked to judge use-friendliness of the scales.

After completion of the study, one of the scales should be used daily to assess pain in children admitted to a Dutch burns center.

Study design

During a period of one year, nurses will observe children between 0 and 4 years of age using two pain observation scales. Pain observations will be performed two times a day in rest and immediately after dressing change procedures are completed.

Study burden and risks

Children who will be observed do not experience any hindrance.

Nurses will observe the children two times a day at rest and during wound dressing changes. Wound dressing procedures do not have any other course compared with standard care. Nurses report their observations after completion of the procedure. There will not be any changes in standard pain care procedures.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years)

Inclusion criteria

All children aged 0 to 4 years admitted to a Dutch burns center, not suffering from mental or physical retardation.

Exclusion criteria

Mental or physical retardation

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 01-07-2006

Enrollment: 100

Type: Actual

Ethics review

Approved WMO

Date: 29-05-2006

Application type: First submission

Review commission:

BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek
(Assen)

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	NL12178.030.06