Comparison of two computerized anaesthesia delivery system: pain and pain- related behaviour in children on two sequential dental visits.

Published: 06-12-2010
Last updated: 02-05-2024

The aim of this study is to compare the pain and distress response of children during the application of local anaesthesia injection using a computerized device (the Wand ® or the Sleeper One®) and during the following dental treatment.

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

Summary

ID

NL-OMON34873

Source
ToetsingOnline

Brief title
painbehavior of children at the dentist

Condition

- Other condition

Synonym
anesthesia to prevent pain, pain during local anesthesia

Health condition

caries

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: anesthesia, pain, sleeper one, wand

Outcome measures

Primary outcome

wand, sleeper one

Secondary outcome

age, first or second treatment

Study description

Background summary

Of Dutch children aged 4 to 11 years, 14% is afraid of dental treatment. An important factor which makes dental treatment as unpleasant is the pain a treatment can bring. With the improvement in detistry is the pain during the dental treatment decreased. However, the local anesthesia is for both children and adults the most anxiety-producing procedure at the dentist.
The presence of anxiety in children can result in behavioral management problems that makes treatment difficult. One possibility to reduce this behaviorproblems is to try to reduce the pain and discomfort during treatment to a minimum. Increasing the injection time has helped in reducing pain during local anesthesia. The pain during the anesthetic injection is partially caused by the high pressure on the nerve during the injection. Increasing the injection time , the pressure on the nerve cells is limited.
When WAND ® and Sleeper One ® are used, both local anesthetic delivery systems for medical and dental use, the amount of anesthetic liquid that is injected controlled by a computer, the pressure is lower than the gums can endure. The gums can therefore absorb the liquid gradually and reduces the likelihood of pain to a minimum.
Research into the effectiveness of the WAND ® in reducing pain and behavioral problems of children gives mixed results. Previous research by J. Versloot

showed the success of a computer-controlled anesthesia, but gave the disadvantage of longer proceduretime. The Sleeper One is a new variant on the market with a faster turnaround and a higher expected comfort.

Study objective

The aim of this study is to compare the pain and distress response of children during the application of local anaesthesia injection using a computerized device (the Wand ® or the Sleeper One®) and during the following dental treatment.

Study design

The study is a prospective randomized cross- over model with two treatment sessions in a patient whereby one of the two local anaesthesia techniques were used.
Randomization of the techniques are performed by using a randomization list generated by SPSS.

Intervention

The patient will get anesthesia with WAND ® or the Sleeper One ® method. Each patient undergoes two operations in which one of the two stunning devices used

Study burden and risks

The children treated for caries at the center, always receive a local anesthetia. Both systems are similar and used interchangeably. This research provides only guidance to the choice of the anesthesia system.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

All subjects were referred to a pediatric dentistry practice by their home dentist. The subjects are selected based on the following criteria: age between 4 and 6 years, and at least two restorative treatments.

Exclusion criteria

no special needs education following, no communication problems

Study design

Design

Study type:	Observational invasive
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2011

Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	06-12-2010
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	NL30999.029.10