Reflection spectroscopy for the age determination of bruises in children.

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

Summary

ID

NL-OMON44500

Source
ToetsingOnline

Brief title
Age determination of bruises in children.

Condition

- Injuries NEC

Synonym
bruise, contusion, haemorrhage, hematoma

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Agentschap NL - IOP Photonic Devices

Intervention

Keyword: bruise, hematoma, spectroscopy

Outcome measures

Primary outcome

The recordings consist of spectral images of the bruise. Based on this dataset

the areas of the hemoglobin and bilirubin can be determined.

The development of these areas gives an overview of the healing process of the

bruise. This information will be used for the validation and optimization of

our 3D computer model for the age determination of bruises.

Secondary outcome

na

Study description

Background summary

Child abuse is a major problem that is more and more acknowledged by our society. The incidence in the Netherlands is estimated to be 118.200 in 2010. Which equals 30 cases for every 1.000 children in the range of 0 to 17 years old. From these abused children an estimated 40 die as a consequence of the abuse. The incidence is rising.

A descriptive definition of child abuse is given by the World Health Organization (2006a): "Child abuse or maltreatment constitutes all forms of physical and/or emotional ill-treatment, sexual abuse, neglect or negligent treatment or commercial or other exploitation, resulting in actual or potential harm to the child's health, survival, development or dignity in the context of a relationship of responsibility, trust or power."
Every form of child abuse can have severe consequensence for the mental, physical and general well-being of the child. Both short- and long-term effects are the increased risk of a decreased psychosocial development, drug abuse, depression (suicidality), fear and behavioral problems.

The need for an objective and non-invasive technique for the age determination

of bruises in indicated by the specialists involved in the diagnosis of child abuse. The age of the bruise is one of the factors where the physicians look at in cases of suspected child abuse (after all: this information can be used to ex- or include a suspect).

Researchers in the department of Biomedical Engineering & Physics developed a method for a non-invasive age determination of bruises using hyperspectral imaging and a 3D computer model. This method is tested on adult volunteers. Results show the possibility to determine the age of a bruise with an accuracy of 3 hours. [Barbara Stam; Thesis: Three dimensional modeling of bruise evolution for improved age determination, 2012].

In the intended application of this method the focus will be mainly on the age determination of bruises in children. Since the kinetics of the different biological processes during the healing of a bruise in children is different than in adults it is necessary to validate this method in children of minor age.

When the results of this research indicate that it is possible to determine the age of a bruise in children, using the hyperspectral imaging system en the 3D computer model then this method will be able to serve as an objective tool in the diagnosis of child abuse.

Study objective

The goal of this study is to develope and validate a non-invasive method for the age determination of bruises. This method is tested on adult volunteers. We expect differences between the healing proces of bruises in adults and children.To be more specific, we expect differences between the conversion of hemoglobin into bilirubin and the diffusion of these compounds through the skin. These are important parameters for our 3D computer model.
We want to perform measurements in children with bruises where the time of occurrence of the bruise is known. Knowledge of the healing process of bruises in children gives us the opportunity to validate the technique for the relevant target group.

Study design

Observational study

Study burden and risks

De burden for the minor human subjects is minimal. The pediatricians involved in this research indicated that participation to the measurement is viable for the intended human subject groep.
The measurement does not involve or introduce a risk for the minor human

subjects and
takes up 10 minutes per measurement of which 1-2 minutes will be taken up by the actual spectral measurement. In total a maximum of 5 measurements will be performed, with a maximum of 1 measurement per day.

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

age 2 - 17 years old
consent from child and parent(s)/guardian
the age of the bruise is known up to a certainty of 3 hours
no injury to the skin above the bruise (intact)

Exclusion criteria

leasion to the skin above the bruise
the human subject is too traumatized due to the accident/cause of the bruise
use of cytostatics

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-10-2015
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	25-08-2015
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	NL48226.018.15