Research into the influence of cooling on bruise development measured using reflection spectroscopy.

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Injuries NEC
Study type	Observational non invasive

Summary

ID

NL-OMON42673

Source
ToetsingOnline

Brief title
Influence of cooling on bruise development

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, cooling, hematoma, spectroscopy

Outcome measures

Primary outcome

The measurements consist of spectral images of the bruise. Based on these images the size of the hemoglobin and bilirubin areas can be determined. Using the change of the size of these areas over time the healing of the bruise can be monitored and used to see the possible differences between the healing of the cooled and the uncooled bruise.

Secondary outcome

na

Study description

Background summary

Child abuse is a major problem that is more and more acknowledged by our society. Research of the incidence of child abuse in the Netherlands in 2010 estimates more than 118.000 cases of child abuse among children in the age of 0 to 18 years old (3% of the total population).

Diagnosis of child abuse by a for example a pediatrician is based on certain factors. One of these factors is the determining the presence of (multiple) bruises. Knowledge on the age of the bruise can play a very important role in the determination whether it is a case of abuse. At this moment in time it is not possible to objectively and accurately determine the age of a bruise. To make this possible in the future the department of Biomedical Engineering and Physics is developing a reliable, patient friendly method for the age determination of bruises.

Using a spectral camera they perform (non invasive) measurements on a bruise. This camera measures the absorption of different colors of light and makes it possible to determine the chemical information of the measured surface per pixel. This makes it possible to detect the different components in a bruise

(hemoglobin, bilirubin) and determine the area where these components are present in higher concentrations. For the age determination the change in size of these areas is essential. Using the specially developed 3D model for the age determination of bruises the age of the bruise can be determined based on the size of the areas of hemoglobin and bilirubin.

Previous research: The basis of a similar technique lies in Norway, at Trondheim University. There tests are performed on volunteers showing that it is possible to determine the age of a bruise with an accuracy of 1 day. Researchers in the department of Biomedical Engineering & Physics developed and improved this method method with which they are able to determine the age of a bruise with an accuracy of 3 hours.

Research question: Does cooling of the bruise have an effect on the healing process?

Study objective

To determine the accuracy and robustness of this method it is necessary to validate it. In the past some successful studies have been performed in adult volunteerd. However we would like to investigate the influence of induced changes to the healing process. By this we mean that the healing process of the bruise can be influenced by treating the bruise using methods which are said to have a possitive or negative effect on the healing of the bruise.

On the internet there is a lot of speculation on the possitive effect of cooling on the healing process of the bruise. It is said that due to the cooling the arteries will shrink preventing the bruise from increasing in size. It also prevents the spread of blood to other locations in the body where it does not belong. Other resources only indicate that the cooling relieves the pain.
Because the effect of cooling on the healing process is unclear and might have an influence on the model for the age determination of bruises we would like to investigate this into more depth.

Study design

In this study research will be performed on healthy volunteers. For every participant we will make 2 bruises, 1 on each forearm, in a controlled manner. One of these bruises will be cooled multiple times during the healing, the other bruise will heal in a normal manner. The bruises will be measured over time using a spectral camera to get a good insight of the healing of the bruise.

Study burden and risks

2 bruises will be inflicted. 1 on each forearm.
These bruises will be measured 10 times. Every measurement will take 5-10 minutes and will be spread over 2 weeks.

Furthermore the bruise will have to be cooled for 2 days, 3 times a day for 15 minutes.
The total burden will be approximately 4 hours.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

18 years and older
participation is on voluntary basis

available during research period

Exclusion criteria

hematologic disorders
osteoporoses
connective tissue disorders that influence the formation on hematoma

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	21-04-2016
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	NL53322.018.15