Resolution of subcutaneous haemtomas, comparison of upper versus lower extremity in healthy adults

Published: 12-08-2020
Last updated: 09-04-2024

It is known that physical examination and visual inspection of haematomas is unreliable and therefore there is a need for a reliable and validated method. This to be able to create a timeline which can be used to identify or exclude potential...

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

Summary

ID

NL-OMON49223

Source
ToetsingOnline

Brief title
Resolution of subcutaneous haemtomas

Condition

- Other condition

Synonym
Haematomas - bruises

Health condition

Niet van toepassing

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: dating, forensics, Haematoma, medicine

Outcome measures

Primary outcome

Timing of healing haematomas on the lower arm and lower leg.

Secondary outcome

Accuracy and robustness of spectroscopy to date haematomas in a larger

population of adult volunteers.

Study description

Background summary

In forensic medicine haematomas are important findings in physical abuse. Physical abuse occurs at any age, although in mainstream media most of the attention is focussed on child abuse and to a lesser extend to elder abuse. Child abuse is an important social and medical problem with an increasing number of reported cases annually. In the Netherlands studies have shown that annually approximately 118.000 children (3% of all children) aged 0-18 are the victim of physical abuse. With respect to elder abuse the figures are less clear but the estimate is that annually 200.000 elderly are victim of abuse, this includes all forms abuse not just physical.

Study objective

It is known that physical examination and visual inspection of haematomas is unreliable and therefore there is a need for a reliable and validated method. This to be able to create a timeline which can be used to identify or exclude potential suspecdts. A potential tool that can be used by first line forensics is the use of spectroscopy. With the aid of a spectral camera it is possible to assess the amount of absorption of a bruise and thus geographically map the chemical information. This makes it possible to detect chemicals in the skin

(e.g. haemoglobin and bilirubin) and to assess the size of the area where these chemical are deposited. For age assessment, or the change over time, of a haematoma this assessment of haemoglobin and bilirubin is essential. Using a 3D model of healing haematomas, developed in the Amsterdam Medical Center, it is possible to assess the age of the haematoma under investigation.
In order to assess the accuracy and robustness of this method it is mandatory to validate in. In the past several successful in-vitro studies on blood stains and in-vivo studies in adults have been done. However, to date there are no studies in the influence of the location on the healing process of haematomas. For forensic purposes this is an important question, because if there is an influence of location on the healing process, this approach might be less reliable and not directly applicable in court of law.

Study design

Using a previously published standardised methods haematomas will be inflicted in adult healthy volunteers. This method consists of a 1 meter tube positioned vertically through which a 400 gram weight will be dropped on the extremity. The location of the induced bruise will be marked using a waterproof marker. The locations that will be assessed in this study are the volar side of the dominant lower arm and the calf on the ipsilateral side.
Prior to the experiment a spectral photo will be obtained, followed by a spectral photo directly after impact. Spectral photography will be repeated in 24 hour intervals on the next 6 days.

Study burden and risks

We don*t expect complications or side-effects in this study. A previous study in healthy adult volunteers showed an average pain score of 4.1 on a scale of 1 * 10.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ

NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Over 18 years of age

Exclusion criteria

Use of oral anticoagulants
Increased bleeding tendency
Osteoporosis

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):	27-08-2020
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	12-08-2020
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	NL73941.018.20