

Dating of injury with new markers in superficial skin biopsies

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In-vivo validation of protein makers in minimal invasive skin biopsies from persons with blunt injuries in different time periods.

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

Summary

ID

NL-OMON53615

Source

ToetsingOnline

Brief title

Dating of injury

Condition

- Other condition

Synonym

bruises, hematomas

Health condition

letsel - bloeditstoringen

Research involving

Human

Sponsors and support

Primary sponsor: Amsterdam UMC

Source(s) of monetary or material Support: ZONMW

Intervention

Keyword: Criminal law, Dating of injury, Hematomas, Violence

Outcome measures

Primary outcome

Expression of protein markers in superficial layers of the skin (epidermis and superficial dermis), detected and measured by immunohistochemical analysis in skin biopsies from bruises as follows:

- the quantity of the protein marker or an (intensity) score reflecting the presence/ absence of the protein marker and,
- the cellular location (keratocytes, fibroblasts or extracellular matrix) of each marker

Secondary outcome

N/A

Study description

Background summary

Evidence-based methods to date injury, especially in living subjects, are lacking.

Developing an evidence based method for injury dating will improve forensic medical expertise and be greatly beneficial for the legal process in fact-finding of crimes.

Study objective

In-vivo validation of protein makers in minimal invasive skin biopsies from persons with blunt injuries in different time periods.

Study design

Cross-sectional observational study

Intervention: minimal invasive skin biopsies from persons with bruises in different time periods

Study burden and risks

This study involves an once-off skin biopsy, no additional visits are needed. The health risk of the skin biopsy is low, it is an minimal invasive procedure with little discomfort and minimal medical risks.

Contacts

Public

Amsterdam UMC

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

- Age 18 years or older

- Competent
- Sufficient Dutch/ English proficiency
- Visible bruises caused by external force
- Clear knowledge and preferably proof of the date and time the injury has been sustained
- Informed consent to undergo a skin biopsy and donate the material

Exclusion criteria

- Location of the bruise in the face/ hands/ feet
- Pre-existing inflammatory skin disorders such as psoriasis, SLE and dermatitis
- History of keloid formation or hypertrophic scar formation
- Relevant medication use such as anticoagulation drugs
- Skin injury such as lacerations
- Underlying fractures of bone
- Sexual assault
- Serious emotional/ mental disturbance

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 15-11-2023

Enrollment: 100

Type: Actual

Ethics review

Approved WMO

Date:	27-01-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	01-03-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	17-10-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	22-04-2025
Application type:	Amendment
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	NL81502.018.23