Investigation of the mechanical properties of pathological scars using suction-based Optical Coherence Elastography

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Epidermal and dermal conditions
Study type	Observational non invasive

Summary

ID

NL-OMON55099

Source
ToetsingOnline

Brief title
OCT elastography in pathological scars

Condition

- Epidermal and dermal conditions

Synonym
1. Scars 2. Cutaneous cicatrication

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Health Holland

Intervention

Keyword: Biomechanics, Hypertrophic scars, Keloid, Optical Coherence tomography

Outcome measures

Primary outcome

The main objective of this study is to determine whether OCT-based suction elastometry is a proper tool to quantify elasticity of mature keloid and hypertrophic scars and healthy skin in human subjects.

Secondary outcome

What is the concurrent validity of this device? Do the results correlate with the item *pliability* of the POSAS.

Can we use this device for the analysis of pathological scars. Although this device does not differ tremendously from the Cutometer, the feasibility needs to be addressed in this pilot. Are the measurements practical and timely? Does a single measurement provide sufficient data for the quantification of the above mentioned parameters?

Can this device be used to measure scar specific differences in epidermal thickness

Study description

Background summary

Stiffness and elasticity are important parameters in skin research and clinical practice. These biomechanical factors are affected by both physiological and pathological changes, of which scarring is the most common cause. Increased stiffness in scars is a major part of the disease burden in the case of

hypertrophic scarring and keloids, and is therefore a target for multiple therapies aimed at decreasing stiffness and increasing elasticity. Objective quantification of the biomechanical characteristics of skin may be improved by a multimodal approach: by combining suction-based deformation with Optical Coherence Tomography imaging. This combination will be tested in this research project by means of a novel medisch device developed at the Vrije Universiteit Amsterdam.

Study objective

The main parameter of this study is the objective quantification of the biomechanical properties of skin and keloid/hypertrophic scars, as compared to the golden standard (Cutometer).The discriminating capacity will be tested by comparing healthy skin and pathological scar tissue.

Study design

Pilot study

Study burden and risks

The trial entails 1 measurment moment with 3 measurements:
1) Measurement of scar biomechanics using the novel device (+-15minutes)
2) POSAS questionnaire (Patient and Observer Scar Assessment Scale) (+-15 minutes)
3) Measurement of scar biomechanics using golden standard (Cutometer) (+-15minutes)

Risk assessment (See B24): Negligible

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

* Age: 18 years or older
* Competent
* Keloid or hypertrophic scar.

Exclusion criteria

* Language barrier
* Immature scar/open wounds
* Connective tissue disorders (e.g. Marfan, Ehlers Danlos, Cutis Laxa)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-10-2021
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Suction-based Optical Coherence Elastography device
Registration:	No

Ethics review

Approved WMO Date:	17-05-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-09-2021
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	NL73352.029.21