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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24489

Source
NTR

Brief title
OCE-SCAR

Health condition

Keloid, Hypertrophic scar

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: Health Holland

Intervention

Outcome measures

Primary outcome

Feasibilty of new medical device (validity compared to standard device (Cutometer), duration

of measurement, failed measurements, hypothetical) willingness of subjects to undergo again)

Secondary outcome

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(1), 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.

Study objective

Feasiblity study for new medical device

Study design

1 timepoint, potential subjects are asked to participate after their scheduled outpatient appointment. If subjects are willing to participate, primary and secondary outcomes are assessed by measurement with new device (OCE elastometer), old device (Cutometer), and subjects are asked to fill in Patient scale of the Patient and observer scale assessment scale (POSAS). A comparison of the two devices will be made. Validity of the new device will be made by comparing to stiffness item of the POSAS

Intervention

Measurement with new medical device

Contacts

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Eligibility criteria

Inclusion criteria

Age: 18 years or older
Competent
De novo keloid/hypertrophic scar or follow up for keloid/hypertrophic scar treatment (regardless of treatment modality)

Exclusion criteria

Language barrier
Immature scar, other scar types (hypertrophic, normotrophic)
Connective tissue disorders (e.g. Marfan, Ehlers Danlos, Cutis Laxa)

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-10-2021
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	24-10-2021
Application type:	First submission

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
NTR-new	NL9829
Other	METC VUMC : 2021.0162

Study results