Microcirculation of the vulva in patients with Lichen Sclerosus

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To map microcirculation of the vulva and to evaluate the effects of vulvar LS and the application of topical corticosteroids on microcirculatory parameters with the use of incident dark field imaging (IDFI, Cytocam).

Ethical review	Approved WMO
Status	Will not start
Health condition type	Epidermal and dermal conditions
Study type	Observational non invasive

Summary

ID

NL-OMON45384

Source
ToetsingOnline

Brief title
LIMA-studie

Condition

- Epidermal and dermal conditions

Synonym
Lichen Sclerosus

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Lichen, Microcirculation, Sclerosus, Vulva

Outcome measures

Primary outcome

Differences in measurements of microcirculatory parameters of the vulva between healthy women and women diagnosed with vulvar Lichen Sclerosus, before and after treatment.

Secondary outcome

Not applicable

Study description

Background summary

Vulvar Lichen Sclerosis (LS) is a benign, chronic and progressive dermatological condition characterized by inflammation, epithelial thinning and distinctive dermal changes. The true etiology of this condition remains unknown to date. Vulvar microcirculation is believed to significantly contribute to the health of the vulva. Therefore, altered microcirculation could contribute to the cause or be a consequence of the pathogenesis of vulvar LS.

Study objective

To map microcirculation of the vulva and to evaluate the effects of vulvar LS and the application of topical corticosteroids on microcirculatory parameters with the use of incident dark field imaging (IDFI, Cytocam).

Study design

An observational study.

Study burden and risks

Measurements will be performed which take about 15 minutes. The measurement technique is painless and will cause no harm to the patient. Moreover, the

imaging probe will be covered with a sterile disposable cap. In healthy volunteers this measurement is performed at a single timepoint, in patients the measurement is repeated 2, 6 and 12 weeks achter the start of the treatment. Patients will also fill out a questionnaire, at baseline and after 3 months.

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

Patients with vulvar Lichen Sclerosus based on the presence of characteristic clinical manifestations
Patients who start treatment with topical corticosteroid therapy

Exclusion criteria

Cardiovascular disease
Other inflammatory (skin)disease
Other systemic illness
Medications that could influence the microcirculation

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:	Will not start
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Date:	18-04-2017
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	NL60463.018.17