The long-term consequences of vulvar lichen sclerosus in adult women who were diagnosed in childhood or adolescence

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The goal of this study is to assess the repercussions of juvenile vulvar lichen sclerosus as an adult, and to improve care after the diagnosis of JVLS has been made.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Vulvovaginal disorders (excl infections and inflammations)
Study type	Observational non invasive

Summary

ID

NL-OMON52920

Source
ToetsingOnline

Brief title
Long-term consequences of juvenile vulvar lichen sclerosus

Condition

- Vulvovaginal disorders (excl infections and inflammations)
- Epidermal and dermal conditions

Synonym
Lichen sclerosus

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: long-term follow up, pediatric and adolescent, quality of life, vulvar lichen sclerosus

Outcome measures

Primary outcome

- Vulvar complaints

- Quality of Life

- Sexual health

Secondary outcome

- Obstetric outcome

- Histological characteristics of vulvar lichen sclerosus

Study description

Background summary

Vulvar Lichen Sclerosus is a chronic skin disease with clinical manifestations include itching, pain, bleeding, permanent loss of vulvar architecture and restrictions in daily activities. The estimated prevalence in girls is at least 1:900. The majority of juvenile cases, according to the literature, do not resolve at puberty. Several studies have addressed the quality of life, self-image and the sexual well-being of adult women with vulvar lichen sclerosus, showing a negative effect. These aspects have not been systematically addressed in the population of women who had developed the disease as juveniles.
Through the national pathology database of the Netherlands (PALGA) a database search was performed which found that in the Netherlands in the period 1991-2015 more than 300 women aged <=18 were given a histological diagnosis of vulvar lichen sclerosus. At present over 90% of these women are now aged 16 years or older. By tracing these women and questioning them, often many years after diagnosis, insight can be gained in the possible repercussions of juvenile vulvar lichen sclerosus in adulthood, avoiding recall bias. The results may help clinicians in counseling and treatment of these girls and

women.

Study objective

The goal of this study is to assess the repercussions of juvenile vulvar lichen sclerosus as an adult, and to improve care after the diagnosis of JVLS has been made.

Study design

This is a descriptive study in which the subjects fill in standard questionnaires on dermatological conditions, quality of life and sexuality, augmented with questions relating to their obstetric and relevant medical history.

Participants in the online questionnaires who have stated to be willing to participate in further studies will be invited for a single interview and non-invasive physical examination in the Erasmus MC. Informed consent will again be requested beforehand. In the in-depth interview the experience of having been diagnosed with JVLS will be discussed.

Study burden and risks

There are no risks associated with participation. Subjects may experience being confronted with the previously made diagnosis of vulvar lichen sclerosus as somewhat of a burden.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- histological diagnosis of vulvar lichen sclerosus made by biopsy in the Netherlands in the period 1991 through January 2015
- Age at time of biopsy <= 18 years old
- at least 16 years old as of 1 January 2019

Exclusion criteria

- histological diagnosis is not verified on revision by expert pathologist or the material was not available for revision
- insufficient knowledge of the Dutch language
- not legally competent

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2020
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	20-12-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-07-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-08-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-11-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	01-03-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL63335.078.19