

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

Published: 20-12-2019

Last updated: 09-04-2024

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

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

## Summary

### ID

NL-OMON52920

### Source

ToetsingOnline

### Brief title

Long-term consequences of juvenile vulvar lichen sclerosis

### Condition

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

### Synonym

Lichen sclerosis

### 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 sclerosis

## Outcome measures

### Primary outcome

- Vulvar complaints
- Quality of Life
- Sexual health

### Secondary outcome

- Obstetric outcome
- Histological characteristics of vulvar lichen sclerosis

## Study description

### Background summary

Vulvar Lichen Sclerosis 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 sclerosis, 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  $\leq 18$  were given a histological diagnosis of vulvar lichen sclerosis. 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 sclerosis 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 sclerosis 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 sclerosis as somewhat of a burden.

## **Contacts**

### **Public**

Erasmus MC, Universitair Medisch Centrum Rotterdam

Wytemaweg 80 Wytemaweg 80  
Rotterdam 3015 CN  
NL

### **Scientific**

Erasmus MC, Universitair Medisch Centrum Rotterdam

Wytemaweg 80 Wytemaweg 80  
Rotterdam 3015 CN  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

### Inclusion criteria

- histological diagnosis of vulvar lichen sclerosis made by biopsy in the Netherlands in the period 1991 through January 2015
- Age at time of biopsy  $\leq$  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**

<b>Register</b>	<b>ID</b>
CCMO	NL63335.078.19