



# Interest and willingness to participate in clinical trials on Lichen Sclerosus

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## 2. Introduction

When the pharmaceutical industry develops new drugs to treat Lichen Sclerosus, it is necessary that they test their new drugs on patients with Lichen Sclerosus.

To test new drugs on patients, clinical trials must be set up, with authorization and ethical approval from respective authorities. In these trials, one group of patients receives the active drug, and the second group receives a placebo medication. The term placebo indicates an inactive substance that looks like the active drug but is, in fact, inactive (e.g., a sugar pill). Placebo medications help determine the efficacy of the active medication and help to prevent bias from skewing results.

A clinical trial of a new drug typically has a trial period of 12 weeks.

This means that for a period of 12 weeks, you do not know whether you will receive treatment with the active drug or a placebo without an active substance (and, therefore, will not receive treatment for your disease during the trial period).

In addition, there may be a tapering period of current medical treatment up to the start of the study to ensure that current medical treatment does not affect the results of a study.

This report provides an answer to how long the Danish Lichen Sclerosus patients are willing to refrain from treating with their current drug for a period leading up to the study, with the risk that they will experience a flare-up of their disease.

### 2.1 Limitations

The report is limited to women age 18+ with vulvar Lichen Sclerosus (Lichen Sclerosus on the external genitalia).

The respondents are from Denmark.

### 2.2 Methods

We conducted an online survey in the period 4<sup>th</sup> November 2022 to 7<sup>th</sup> May 2023 via SurveyMonkey.com.

We sent out a link to our questionnaire via:

- publication on our website [www.lichensclerosus.dk](http://www.lichensclerosus.dk)
- mail to all members of the Danish Lichen Sclerosus Association with the title "We need your help for an online survey"
- closed Facebook group for members of the Danish Lichen Sclerosus Association
- closed debate forum and discussion forum for members of the Danish Lichen Sclerosus Association
- the Facebook group "All of Us with Lichen Sclerosus" in Denmark
- public post on chairman Suzanne von Seitzberg's private Facebook profile (shared 5 times)
- public post on chairman Suzanne von Seitzberg's private Instagram profile

The design of the questionnaire can be seen in Appendix 1.

It was possible to skip questions, which is reflected in the total number of responses to the individual questions.

## 3. Results

### 3.1 Data

We received 400 online responses to our questionnaire in the period 4<sup>th</sup> November 2022 to 7<sup>th</sup> May 2023.

Of the responses, 398 are women, and 390 are aged 18 or over.

367 respondents had vulvar Lichen Sclerosus; 22 respondents had both vulvar Lichen Sclerosus and a secondary vulvar condition.

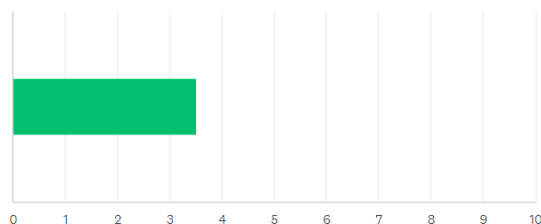
On the specific day for answering the survey, 392 respondents indicated an itch of an average of 3.52 on a scale from 0 to 10, where 0 is no itch and 10 is the worst imaginable, unbearable itch. On the scale, we had indicated the number 5 as moderate itching.

186 responses (47%) stated, that they experienced an itch of 4 or more.

#### **Fig. 1 Question about itch**

*“On a scale from 0 to 10, where 0 is no itch and 10 is the worst imaginable, unbearable itch, how do you experience itching today as a result of your vulvar Lichen Sclerosus?”*

(Number of respondents = 392. 8 respondents skipped this question.)



### 3.2 Willingness to participate in clinical trials

There is a great willingness to participate in clinical trials of a new drug for the treatment of vulvar Lichen Sclerosus.

147 respondents (37%) answered "yes, definitely", and 169 respondents (43%) answered "yes, perhaps." In total, 316 respondents (79% of respondents who stated "yes, definitely" or "yes, perhaps") wanted to participate in a clinical trial, even without having details of the trial itself.

These statistics demonstrate a great interest and willingness to participate in clinical trials for vulvar Lichen Sclerosus treatments.

47 respondents (12%) answered "no, I don't think so" and "no, definitely not" to participate in a clinical trial.

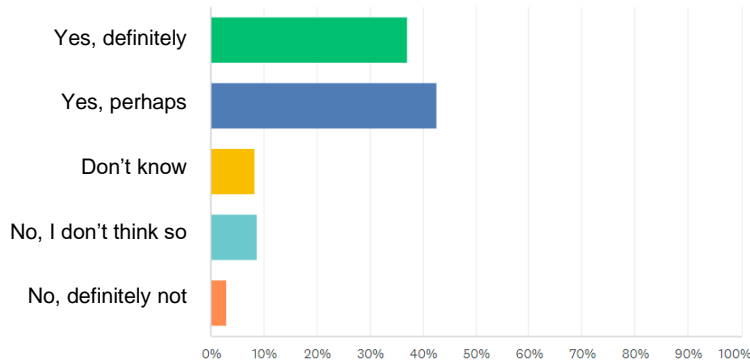
At the end of the questionnaire, there was a paragraph format box wherein participants could share their thoughts or elaborate on their responses. Some respondents stated they have no interest in participating in clinical trials because their Lichen Sclerosus is in remission. Others stated they were worried a trial would cause their Lichen Sclerosus to flare and were concerned about risks.

Furthermore, others stated their Lichen Sclerosus causes them so much pain they did not want to participate in a trial. Finally, some respondents stated they had other vulvar diseases (cell changes or cancer) and were worried, participating in a trial would cause more discomfort.

## Fig. 2 Question about participating in a clinical trial of a new drug for the treatment of Lichen Sclerosus

*“Would you be interested and willing in participating in a clinical trial of a new drug for the treatment of vulvar Lichen Sclerosus?”*

(Number of respondents = 396. 4 respondents skipped this question.)



The statistics change when respondents were given more information about the trial such as telling the new drug is already used to treat another condition via injections and has little side effects.

When presented with this information, 156 respondents (39%) answered "yes, definitely" and 166 respondents (42%) said "yes, perhaps". In total 322 respondents (81%) would participate in a trial. Only 38 respondents (10%) answered "no, I don't think so" and "no, definitely not" to participate in a clinical trial.

If the active drug is to be applied to the vulva and is known to treat other diseases, and you know a little about expected side effects in advance, there is a slightly larger population of people willing to participate in a clinical trial.

This shows the importance of providing information to the patients about the active drug when you are recruiting patients for a clinical trial: What do you know about the drug up front? Is it already used to treat other diseases? Are you aware of any side effects?

In addition, it is also important to tell the patients about the form of the drug (cream, tablets, etc.) and how to dose the drug.

### 3.3 Form of the drug

Overall, there is a general willingness to test new drugs for vulvar Lichen Sclerosus. This willingness varies depending on the type of drug being trialled.

For example, 90% of respondents reported willingness to trial ointments, 81% reported willingness to trial creams, 70% reported willingness to trial oral tablets, 41% reported willingness to trial injections into non-genital sites, and, finally, 25% reported willingness to have injections into the vulva.

Among other forms of drugs or treatment, vaginal tablets, laser treatment, light treatment/infrared, plasters, and diet are suggested.

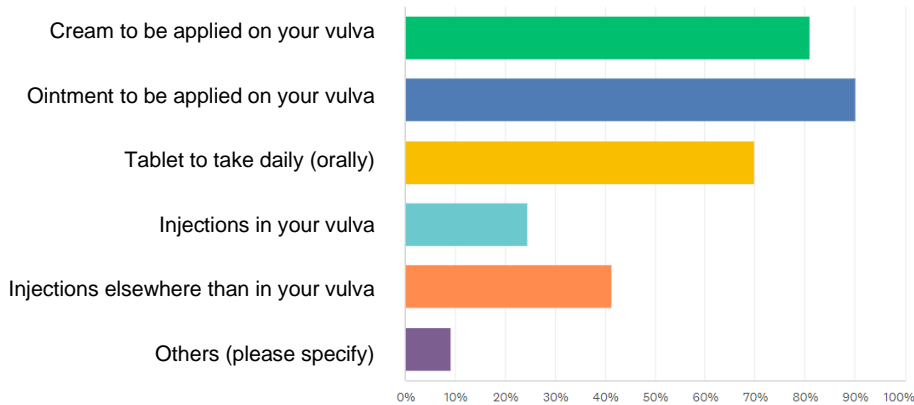
A few respondents indicated that they would not be willing to participate in a clinical trial of a new drug and therefore did not answer the question.

When looking at the difference in the responses between the use of ointment or cream, it is worth noticing that Lichen Sclerosus patients are taught to avoid creams and prefer ointments. A greasy ointment is usually better than a cream, as a cream often contains water, which can have a drying effect on the skin. In addition, creams need to be preserved due to the water content in order to keep better, unlike ointments. Some of these preservatives can cause skin irritation and itching in some patients, and Lichen Sclerosus patients are advised to avoid potential substances that can irritate the vulva.

**Fig. 3 Form of the drug**

“Would you participate in a clinical trial of a new drug for the treatment of vulvar Lichen Sclerosus if the drug was in the following form (tick all acceptable forms)?”

(Number of respondents = 370. 30 respondents skipped this question.)



### 3.4 Take a break from usual drugs

When looking at the period leading up to a trial, it will often be necessary to take a break from using your usual drug to ensure that these drugs do not affect the trial results.

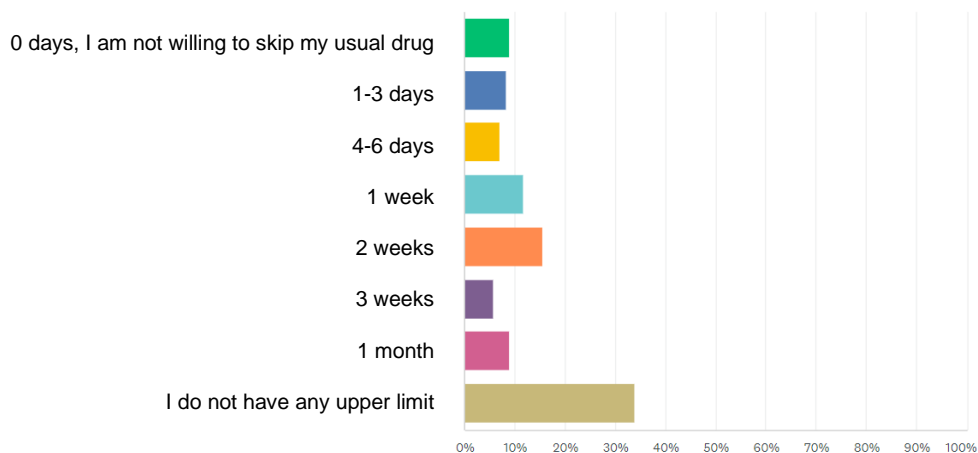
For this question, the results showed 130 respondents (34%) had no limit to the length of time with which they would take a break from their current treatment plan. 116 respondents (29%) stated, they would be willing to stop their current treatment plan 2 weeks to 1 month before the trial, despite the risk of worsening their symptoms or disease when left untreated.

104 respondents (26%) indicated from 1-3 days and up to 1 week, while only 34 respondents (9%) indicated they would not be willing to take a break from using their usual drug.

**Fig. 4 Take a break from using your usual drug in a period up to the trial**

” Most clinical trials imply that you must not use other drugs for a period leading up to the start of the trial. This means that you must not treat with your usual medicine (Dermovate, Protopic or similar) for a given period until the trial starts. How long before the start of a clinical trial is the maximum you would be willing to take a break from using your usual drug?”

(Number of respondents = 384. 16 respondents skipped this question.)



### 3.5 Take a break from care products

When participating in clinical trials, patients will often be asked not to use other care products in a period leading up to a trial to ensure these care products do not affect the trial results.

In this section, 77 respondents (20%) said they would be willing to take a break from care products for as long as necessary. 86 respondents (22%) said they would be willing to stop care products between 2 weeks to one month before the trial.

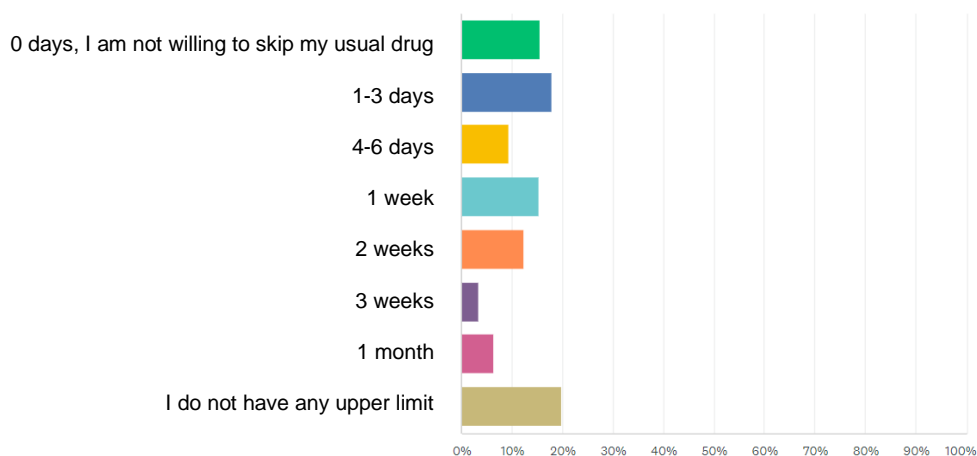
164 respondents (41%) stated, they would stop care products up to a maximum of 1 week prior to the trial. Finally, 60 respondents (16%) said they would not be willing to stop care products prior to the trial.

This shows less willingness to take a break with care products compared to take a break with drugs in the run-up to a clinical trial among Lichen Sclerosus patients. The reason is probably the fact that Lichen Sclerosus patients are used to taking a break from their drugs when their symptoms have subsided. Many use their drugs once a week during quiet periods and only daily when their symptoms/disease activity flares up. Whereas they use their care products daily to keep the skin soft and supple with a good fat barrier.

**Fig. 5 Take a break from using care products in a period up to the trial**

*” Most clinical trials imply that you must not use care products (e.g., Dr. Warming Critical Care, Ceridal skin oil, White Wonder, Locobase, Danatekt, A-derma Exomega Control) for a period leading up to the start of the trial. This means that you must not ointments, oils, creams, or other for a given period until the trial starts. How long before the start of a clinical trial is the maximum you would be willing to take a break from using your usual care products?”*

(Number of respondents = 387. 13 respondents skipped this question.)



### 3.6 Numbers of control visits during the trial

During a clinical trial, it will be necessary to go to a check-up with a doctor to monitor the drug's effect on the disease.

In the paragraph formatted box at the end of the questionnaire, some have commented that it is important that this check-up is carried out by a doctor with expert knowledge of Lichen Sclerosus. This is presumably because many Lichen Sclerosus patients experience being met by general practitioners and even specialists who need more knowledge and experience in treating Lichen Sclerosus.

It must be safe and secure to participate in a clinical trial, and it is crucial for patients that they are met by professional and empathetic doctors when they need to be treated or checked for their condition.

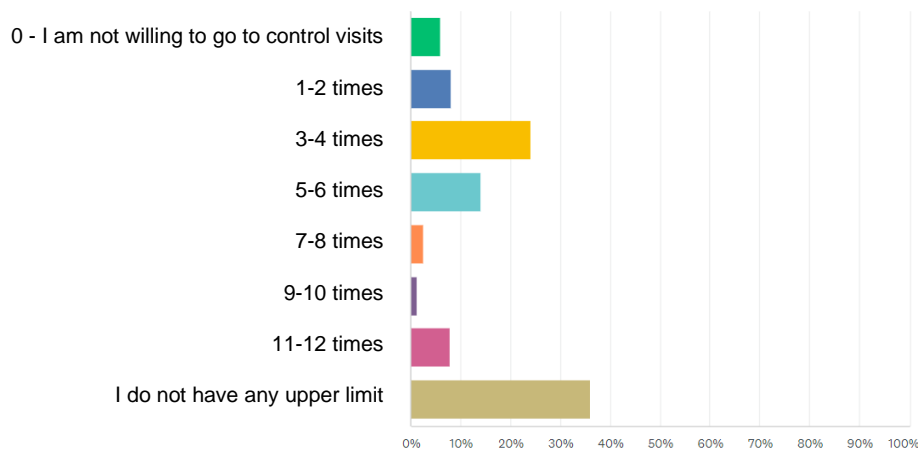
For a trial with a duration of 12 weeks, 139 respondents (36%) stated willingness to see a doctor for a check-up as many times as necessary. 93 respondents (24%) are willing to show up for 3-4 check-ups. Finally, 23 respondents (6%) were unwilling to show up for check-ups (presumably folks who were not willing to participate in the trial).

Some have commented that it is important that the visits can be planned outside their working hours so that they are not absent from work. Others have commented that the transportation time is crucial to their participation in a trial. The location of the trial must be pretty close.

**Fig. 6 Number of control visits during the trial**

*“During the trial period of 12 weeks, it will be necessary to see a doctor a number of times to monitor the drug's effect on the disease. What is the maximum number of visits you would be willing to make to a doctor during the trial period of 12 weeks?”*

(Number of respondents = 385. 15 respondents skipped this question.)



## 3.7 Photo documentation

We are aware of and acknowledge the fact that it can be helpful to take photos of the skin in order to see any changes in the skin during the trial. This is the reason why, we asked about vulvar Lichen Sclerosus patients' willingness to having a photo of their vulva taken during a trial.

Overall, this section showed great willingness for photos to be taken during the trial. 174 respondents (44%) responded “yes, definitely” and 138 respondents (35%) responded “yes, perhaps” to having their photo taken.

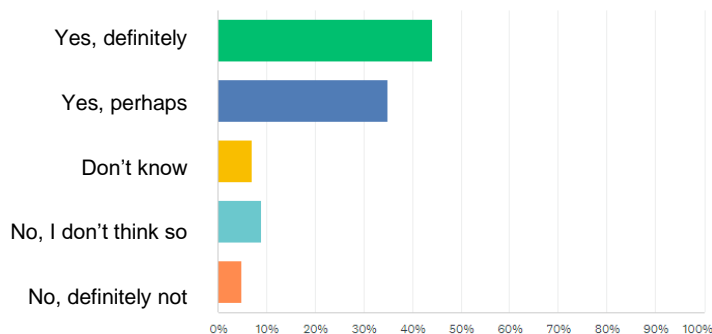
Only 54 respondents (14%) said "no, I don't think so" or "no, definitely not" to having their photo taken.



### Fig. 7 Photo documentation

Would you participate in a clinical trial of a new drug for the treatment of vulvar Lichen Sclerosus if a photo is taken of your vulva (your external genitalia) to document changes?

(Number of respondents = 394, 6 respondents skipped this question.)



## 3.8 Other comments

In sum, there is an overwhelmingly positive response whereby patients with vulvar Lichen Sclerosus are willing to participate in clinical trials to help improve treatment options.

Many respondents stated the importance of receiving adequate information about the kind of drug, its known effects, how it is used, expected side effects, etc., for them to decide to participate or not.

Obstacles to participating in trials include geographical location and transportation times and having it not interfere with their working hours.

Trial-related concerns include giving up their daily care products and worries about their condition worsening if they are in the placebo group. Many respondents needed confirmation about the doctors being experts in Lichen Sclerosus. Finally, folks stated the desire to be able to leave the trial if their condition flared too badly.

In the open comment field at the end of the survey (where we ask if there are other things they want to mention about participating in clinical trials), the following comments were given, showing the importance of finding a better treatment for vulvar Lichen Sclerosus:

- Everything that can help treat/stop Lichen Sclerosus is important!
- It is a terrible disease (fortunately, I was only diagnosed about 5 years ago... I am 71 years old now), and I would like to help find an effective treatment, because it is so stressful, all the young people, even children, who get it. Hope there can be more focus and widespread knowledge in the medical world and among researchers. Glad someone is doing something.
- In order for me to participate, there absolutely must be a LOT more information, as it is a fairly demeaning illness/condition I am in, already, in fact the very worst of all my illnesses.
- I would find it very difficult to go without treatment and prevention with fatty creams and Dermovat respectively during periods of active flare-ups. At the same time, I would very much like to support the research for better treatment of Lichen Sclerosus.
- A really miserable disease which considerably reduces the quality of life. Hopefully, more research can make a difference.
- Since this disorder is quite unknown and very unpleasant, I will go a long way to help research for an improved treatment.
- Not particularly interested, as I am largely symptom-free with Dermovat and fatty cream. I am afraid that the disease will flare up again without my usual treatment.
- I live in the Faroe Islands. It is a bit difficult to live in Denmark as long as the trial is running. However, I will do everything for a better everyday life, including moving to Denmark while I am a part of a trial.

- I am most reluctant to participate due to the fear of receiving a placebo. This would mean 12 weeks without treatment and associated itching and possibly changes in the vulva.
- I am very ambivalent and am currently not willing to expose myself to a worsening of my condition, as at the moment I'm OK tolerable... And my notions of being exposed to etching, itching or other unpleasantness things down there if I participate in a trial. On the contrary, I feel like a coward for not daring to expose myself... Imagine if the trials could turn out to be a miracle and our disease could be cured by being brave enough to participate in a trial.
- I am not yet so bothered by my disease, but challenged by scratches and tenderness during sex. So, anything that can make the skin healthy again is interesting.
- The possibility of being able to stop the trial and get guidance if my Lichen Sclerosus suddenly goes crazy because the rhythm with the usual products and medical drugs is broken. If the condition worsens, I will stop the trial immediately.

# 4 Conclusion

Our report shows a great interest and willingness among Danish women to participate in clinical trials for better treatment of vulvar Lichen Sclerosus.

Lichen Sclerosus is a chronic debilitating disease that greatly affects the patients' quality of life. Therefore, they are willing to go far to test new treatment methods in order to find a better treatment that can provide symptom relief and improvement to their mental health and sexual health. In sum, they need improvement to their quality of life.

They are willing to try many different drugs in many different forms under controlled conditions and a safe environment on a well-informed basis.

There is broad support for participating in clinical trials all over Denmark. Clinics and doctors that are already known for good and professional treatment of Lichen Sclerosus are preferred for testing a new drug during the trial period.

## 4.1 Contact information

Feel free to contact the Danish Lichen Sclerosus Association on tel. +45 61 15 93 15 or [mail@lichensclerosus.dk](mailto:mail@lichensclerosus.dk) if you are interested in learning more about Lichen Sclerosus or support the work of our association.

## Appendix 1: The survey

### Interest and willingness to participate in clinical trials on Lichen Sclerosus

When the pharmaceutical industry develops new drugs to treat Lichen Sclerosus, at some point they want to test their new drugs on patients with Lichen Sclerosus.

This is done in clinical trials, approved by the authorities, where a number of patients receive the active drug and a control group receives a placebo agent. Placebo is a term for an inactive substance that looks like the drug or treatment being tested. It is used in clinical trials to test the effect of the drug or the treatment, to find out whether the tested drug or treatment works because of its active ingredient or because of the patient's or doctor's expectations to the treatment.

With this survey, we want to uncover the interest and willingness of Danish Lichen Sclerosus patients to participate in clinical trials on Lichen Sclerosus under different conditions.

The survey is limited to women 18+ years with vulvar Lichen Sclerosus (Lichen Sclerosus on the external genitalia).

A clinical trial of a new drug typically has a trial period of 12 weeks.

This means that for a period of 12 weeks you do not know whether you will receive treatment with the active drug or a placebo without an active substance (and therefore will not receive treatment for your disease during the trial period).

#### 1. Your gender?

- Female
- Male
- Other

#### 2. Your age?

- Under 18 years
- Over 18 years
- Don't know

#### 3. Do you have vulvar Lichen Sclerosus (and not other vulvar diseases)?

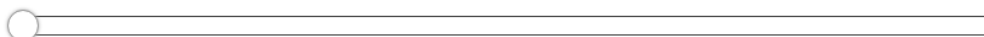
- Yes, I only have vulvar Lichen Sclerosus
- Yes, I have vulvar Lichen Sclerosus and other vulvar disease(s)
- No, I don't have vulvar Lichen Sclerosus
- Don't know

#### 4. On a scale from 0 to 10, where 0 is no itch and 10 is the worst imaginable, unbearable itch, how do you experience itching today as a result of your vulvar Lichen Sclerosus?

0 – no itch

5 – moderate itch

10 – worst imaginable, unbearable itch



#### 5. Would you be interested and willing in participating in a clinical trial of a new drug for the treatment of vulvar Lichen Sclerosus?

- Yes, definitely
- Yes, perhaps
- Don't know
- No, I don't think so
- No, definitely no

**6. Would you participate in a clinical trial of a new drug for the treatment of vulvar Lichen Sclerosus if the drug was in the following form (tick all acceptable forms)?**

- Cream to be applied on your vulva
- Ointment to be applied on your vulva
- Tablet to take daily (orally)
- Injections in your vulva
- Injections elsewhere than in your vulva
- Others (please specify)

**7. Would you participate in a clinical trial of a new drug for the treatment of vulvar Lichen Sclerosus if you were told that it is a topical drug where the active substance is already used today to treat another disease via injections (injections) without a lot of side effects?**

- Yes, definitely
- Yes, perhaps
- Don't know
- No, I don't think so
- No, definitely no

**8. Would you participate in a clinical trial of a new drug for the treatment of vulvar Lichen Sclerosus if a photo is taken of your vulva (your external genitalia) to document changes?**

- Yes, definitely
- Yes, perhaps
- Don't know
- No, I don't think so
- No, definitely no

**9. Most clinical trials imply that you must not use other drugs for a period leading up to the start of the trial. This means that you must not treat with your usual medicine (Dermovate, Protopic or similar) for a given period until the trial starts. How long before the start of a clinical trial is the maximum you would be willing to take a break from using your usual drug?**

- 0 days, I am not willing to skip my usual drug
- 1-3 days
- 4-6 days
- 1 week
- 2 weeks
- 3 weeks
- 1 month
- I do not have any upper limit

**10. Most clinical trials imply that you must not use care products (e.g., Dr. Warming Critical Care, Ceridal skin oil, White Wonder, Locobase, Danatekt, A-derma Exomega Control) for a period leading up to the start of the trial. This means that you must not ointments, oils, creams, or other for a given period until the trial starts. How long before the start of a clinical trial is the maximum you would be willing to take a break from using your usual care products?"**

- 0 days, I am not willing to skip my usual drug
- 1-3 days
- 4-6 days
- 1 week
- 2 weeks
- 3 weeks
- 1 month
- I do not have any upper limit

**11. During the trial period of 12 weeks, it will be necessary to see a doctor a number of times to monitor the drug's effect on the disease. What is the maximum number of visits you would be willing to make to a doctor during the trial period of 12 weeks?**

- 0 - I am not willing to go to control visits
- 1-2 times

- 3-4 times
- 5-6 times
- 7-8 times
- 9-10 times
- 11-12 times
- I do not have any upper limit

**12. If there was a clinical trial of a new drug for the treatment of Lichen Sclerosus, in which region would you like to see a doctor to check the effectiveness of the drug?**

- Region North Jutland
- Region Central Jutland
- Region South Denmark
- Region Zealand
- Region Copenhagen

**13. If there was a clinical trial of a new drug for the treatment of Lichen Sclerosus, which doctor would you like to see to check the effectiveness of the drug?**

**Please state the name of the doctor/clinic/hospital as well as postcode and city.**

**14. If there is anything else you find relevant in relation to your interest and willingness to participate in clinical trials on vulvar Lichen Sclerosus, you can add your comments here:**