Explanatory documents

Clinical Research
"A Multicenter Randomized Controlled Study of the Efficacy and Safety of Cepharanthine for Oral Lichen Planus"
(Research name: the COLE study)
Request to participate

Facility Name:

Version number: 1.1
Date of creation: September 20th, 2022
1. Introduction

At our hospital, we are conducting research to develop better treatment methods and diagnostic methods in order to provide safe, high-quality, advanced medical care to patients. This is called "clinical research," and with the cooperation of patients, we investigate whether treatment and diagnostic methods are effective or safe, and to prevent and elucidate the causes of diseases.

This booklet is a document that explains clinical research. Please read this document carefully and consider whether you agree to participate in a clinical study. If you have any questions from this explanatory document, please do not hesitate to ask your doctor or consultation desk at any time.

2. Clinical research for which we ask for cooperation

"A Multicenter Randomized Controlled Study of the Efficacy and Safety of Cepharanthine for Oral Lichen Planus" (the COLE study) is an example of a specific clinical study that is subject to the Clinical Trials Act. The Clinical Trials Act was enacted in April 2018 with the aim of ensuring public trust, including for subjects of clinical research, and contributing to the improvement of health and hygiene, by making clinical research that clarifies the efficacy and safety of drugs, among other things, a legal requirement.

Specific clinical research conducted at our hospital is examined by the Certified Clinical Research Review Committee to determine whether there are any problems with the protection of human rights and safety and scientific feasibility of the research participants, and based on the opinion, only those approved by the hospital director are conducted. In addition, since this research falls under the category of Specified Clinical Research, we have submitted a research implementation plan to the Minister of Health, Labour and Welfare in accordance with the Clinical Research Act.

The clinical study is scheduled to be conducted from the announcement date of the implementation plan until March 31, 2025, and will involve 50 patients. If you decide to participate
in this study, the expected participation period will be approximately 8 weeks for outpatient follow-up.

3. Research Organization and Principal Investigator of this study

This clinical research is conducted mainly by the Department of Oral Surgery, Nara Medical University Hospital.

Principal Investigator:

Takahiro Yagyuu, Department of Oral and Maxillofacial Surgery, Nara Medical University Hospital

Responsible Investigator:

Takahiro Yagyuu, Department of Oral and Maxillofacial Surgery, Nara Medical University Hospital

Kazuhiko Yamamoto, Department of Oral and Maxillofacial Surgery, Nara Prefecture General Medical Center

Tsutomu Sugiura, Department of Oral Surgery, Minami Nara General Medical Center

Research supervisor:

Professor Tadaaki Kirita, Department of Oral and Maxillofacial Surgery, Nara Medical University Hospital

4. Reasons for selection for clinical research

① About your illness

Ora lichen planus is a chronic and intractable disease characterized by abnormalities in the stratum corneum of the oral mucosa. It is an inflammatory disease that affects the oral cavity and can be debilitating. The condition forms bilateral white lacy (reticulated) lesions on the
mucous membrane of the oral cavity and is difficult to cure completely, requiring lifelong follow-up. Symptoms can range from asymptomatic to painful enough to interfere with daily life, but unfortunately, there is no definitive cure. Steroid ointment can be used as a coping treatment, but it is challenging to use it for an extended period as it may induce infection.

2 About the drugs used in this clinical study

The drug being used in the COLE study is cepharanthine. Cepharanthine is a naturally derived organic compound classified as an alkaloid that has antiallergic and immune function enhancement properties. In Japan, it is used as a medicine for alopecia areata and leukopenia due to radiation therapy. Although the use of cepharanthine for lichen planus differs from the nationally approved indications, effects, and doses, it is empirically recognized to relieve symptoms. As a result, many clinicians in Japan have been prescribing cepharanthine for lichen planus since 1980, leading to numerous case reports on its efficacy and safety. However, despite its widespread use, cepharanthine has not been studied extensively in the context of lichen planus, hence the need for the COLE study.

3 Purpose of this clinical study

The primary objective of the COLE study is to investigate the therapeutic effects of cepharanthine in patients with oral lichen planus. To ensure the fairness and accuracy of the study’s results, it will be conducted as a randomized controlled trial. In this trial, both the attending physician and the patient will be blinded to which treatment group they are assigned. The patients will be divided into two groups: Group A, which will receive cepharanthine treatment, and Group B, which will receive non-cepharanthine treatment. The patients will be observed for a duration of 8 weeks to evaluate the efficacy and safety of the treatments.

4 Criteria for participation

To be eligible to participate in this study, patients must meet all of the following criteria:
NMU4 (Explanatory documents)

- Be over 20 years old
- Have been clinically or histopathologically diagnosed with oral lichen planus
- Experience pain in the mouth, rated as Grade 2 or 3 in the severity classification of CTCAE v5.0
- Have a Performance Status of 0-3, indicating that they are able to receive outpatient care
- Have provided written consent to participate in the study.

Patients who meet any of the following criteria will be unable to participate in the study:

- Have a history of cepharanthine use
- Have a history of radiation therapy to the oral area
- Are currently receiving or planning to receive systemic anticancer drugs, immunosuppressants, or analgesics
- Have a history of hypersensitivity to dexamethasone oral ointment
- Are pregnant or breastfeeding
- Have a serious liver disease, indicated by AST, ALT, γ-GTP levels $\geq 5$ times the upper limit of the facility reference value, or T-Bil levels more than three times the upper limit of the facility standard value
- Have difficulty providing valid informed consent
- Are judged by the research supervisor to be inappropriate for the study

The final decision regarding eligibility will be made by the responsible physician based on the results of the examination and other factors. It is important to consult with the doctor regarding the study's details, and depending on the individual case, patients may not be able to participate.
Methods of clinical research

If patients agree to participate in the study, they will be randomly assigned to one of two groups, and the study will proceed according to a predetermined schedule. The method of dividing patients into the two groups will be unknown to both the patients and the attending physicians, and patients will not be able to choose their group.

Group A will take cepharanthine at a dose of 30 mg per day, divided into three doses after meals, for a duration of 8 weeks.

Group B will not receive cepharanthine treatment. Both groups will apply a thin layer of dexamethasone oral ointment 0.1% to the affected area three times a day. Instructions for how to apply the ointment will be provided.

Before the start of the study and at the end of the study, patients will undergo predetermined examinations and tests. Even after the end of the research period, patients may be asked to come to the clinic at the discretion of the doctor. Depending on the individual patient's health condition, additional tests and consultations may be required.
### Observation, Inspection and Reporting Schedule

<table>
<thead>
<tr>
<th>Date of visit</th>
<th>Date of registration</th>
<th>4 weeks after enrollment (1 week ±)</th>
<th>At 8 weeks after enrollment (± 1 week)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consent to acquisition</td>
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<tr>
<td>Test drug administration</td>
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<tr>
<td><strong>Medical examination</strong></td>
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<tr>
<td><strong>Interview</strong></td>
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<tr>
<td>Patient background check</td>
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<tr>
<td>Clinical findings (Presence or absence of reticular vitiligo and evaluation of site symmetry)</td>
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<tr>
<td>Observation of adverse events</td>
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<tr>
<td><strong>Observation of lesions</strong></td>
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<tr>
<td>Intraoral photography</td>
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<td>O</td>
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<tr>
<td>Clinical type (classification of symptoms)</td>
<td></td>
<td>O</td>
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<tr>
<td>Measurement of target lesions</td>
<td></td>
<td>O</td>
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<tr>
<td><strong>Pain assessment</strong></td>
<td></td>
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<tr>
<td>Pain assessment (VAS) at rest when drinking room temperature water</td>
<td></td>
<td>O</td>
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<tr>
<td>Pain evaluation at meal time (medical questionnaire)</td>
<td></td>
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<td>O</td>
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<tr>
<td><strong>Medication Check the status</strong></td>
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<tr>
<td>Application status of dexamethasone oral ointment</td>
<td></td>
<td>-</td>
<td>O</td>
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<tr>
<td>Cephalantine medication status (cepharanthine group only)</td>
<td></td>
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<td>O</td>
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<tr>
<td><strong>Blood collection (8ml)</strong></td>
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<tr>
<td>Hematological tests.</td>
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<td>O*</td>
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<tr>
<td>Blood biochemistry test</td>
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<td>O*</td>
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</table>

*Substitute can be substituted by test results performed up to 28 days in advance.

The following consultations, interviews, and examinations will be conducted on the day of
study enrollment, at 4 weeks after enrollment, and at 8 weeks after enrollment:

- Patient background information, including age, gender, history of hepatitis C, and history of thymic tumor
- Clinical disease type, determined based on the diagnostic criteria of oral lichen planus, such as the white type or red type
- Blood test, which will involve drawing 8 ml of blood to assess leukocyte count, erythrocyte count, hemoglobin amount, hematocrit, platelet count, CRP, ALB, AST, ALT, ALP, \( \gamma \)-GTP, ChE, and T-Bil levels
- Visual Analog Scale (VAS) to measure pain intensity when drinking room temperature water, scored on a scale from 0 mm (no pain) to 100 mm (worst pain imaginable). Patients will be asked to draw a line indicating the location of the pain in the mouth.

Pain evaluation: Patients will be asked to report their pain levels when drinking room temperature water, eating, and resting.

- Intraoral photo: A photo of the lesion in the oral cavity will be taken.
- Measurement of lesion size: For white lesions in the oral cavity (such as behind the lips, behind the cheeks, around the tongue, etc.), the longest diameter of each anomaly and scarlet lesion and the entire lesion will be measured directly using a caliper, paper measure, or tongue depressor with scales.

Drugs that cannot be used

During clinical research During the clinical research study, the following drugs must not be used as they may affect the study results:
NMU4 (Explanatory documents)

- Systemic administration of steroids
- Treatment drug for keratosis: Eletretinate (Tigason®)
- Mouthwash

7 After completion of the clinical research study

Treatment options may include the use of cepharanthine oral medication or cancer mouthwash. However, patients should consult with their doctor to determine the most appropriate treatment option for their specific condition.

8 Handling of results after completion of clinical research

This research may provide important insights about your health. In this case, we will inform you of the result.

5. Expected benefits and possible disadvantages

Expected profit

Although cepharanthine used in this study has been prescribed for oral lichen planus for quite some time, it is off-label, and cephalantine for oral lichen planus Not enough research has been conducted on the efficacy and safety of the product. If this study shows the efficacy and safety of cepharanthine for lichen planus, it will provide a certain scientific basis for cepharanthine. Furthermore, this is a major step toward expanding the indications for cephalantin in cooperation with related academic societies, pharmaceutical companies, and governments, and it is expected that many patients will have their symptoms alleviated by...
this treatment in the future.

**Possible disadvantages**

Treatment of oral lichen planus is carried out appropriately, regardless of which group it falls into. Even if you do not receive cephalantin, treatment with the application of steroid ointment, which is the standard treatment for lichen planus, will be minor, so the disadvantages are minor. Possible disadvantages of cepharamethine have been reported during development and after marketing, including:

**Serious side effects**

Shock, anaphylaxis (both frequency unknown)

**Other side effects**

Rash, skin rash, edema (face, limbs), loss of appetite, stomach discomfort, nausea, vomiting, diarrhea, elevated AST, elevated ALT, menstrual irregularities, headache, itching, and dizziness.

The frequency of these adverse events is unknown. If any of these symptoms occur or worsen during the study, patients should immediately inform their attending physician.

Another potential side effect of the study is the development of oral candidiasis as a result of using dexamethasone oral ointment on the affected area. If this occurs, treatment with antifungal agents will be administered. To ensure safe participation in the study, the attending physician will closely monitor the patient's physical condition and laboratory values to identify any undesirable symptoms. If such symptoms are observed, a specialist doctor will provide appropriate treatment. The study may also be discontinued at the discretion of the attending physician if it is deemed necessary to ensure the patient's safety.
6. Other potential remedies for the disease

The current standard treatment for lichen planus is the application of steroid ointments. This will also be the treatment used during the clinical study.

7. Participation and decline of clinical research

After receiving an explanation of this clinical study from your attending physician, you are free to decide whether or not to participate. Declining to participate will not result in any disadvantage, and you will continue to receive the standard treatment for your condition.

If new information arises during the study that may affect your decision to continue, you will be promptly notified and given the opportunity to confirm whether you wish to continue participating.

You may withdraw from the study at any time, and your decision will not affect your treatment. The results of any tests conducted prior to your withdrawal will be used unless you indicate otherwise when notifying us of your withdrawal.

If you have any changes to your intention to participate, not participate, or withdraw from the study, please contact your attending physician.

8. Discontinuation of clinical research

Even after agreeing to participate, there may be cases where you are unable to continue the study or the study is discontinued. In such cases, you may still be asked to undergo further testing if deemed necessary by your attending physician. The following are examples of situations that may result in withdrawal or discontinuation from the study:

- Withdrawal of consent by the participant
- Failure to meet the main conditions for participating in the study after enrollment
Worsening of complications that make it difficult to continue the study

Development of illness or other medical conditions that make it difficult to continue the study

Discovery of pregnancy during the study period

Failure to attend the hospital for testing due to relocation or other reasons

Cancellation of the entire study for any reason

Cancellation of the study by the attending physician due to other reasons deemed appropriate

In any of these cases, your attending physician will discuss the situation with you and provide appropriate medical care.

9. Disclosure of information on clinical research

The outline of this study, which is named "Multicenter randomized controlled trial on the efficacy and safety of cepharanthine R for oral lichen planus (COLE trial)", is based on the Ministry of Health, Labour and Welfare's clinical research and publication system called "jRCT: Japan Registry of Clinical Trials" (https://jrct.niph.go.jp/). No personally identifiable information of individual patients will be registered in the system.

In addition, research results, including summary reports, may be shared with Medisa Shinyaku Inc., which provided funding for the research. However, your personally identifiable information will not be disclosed to any third party without your explicit consent.

10. Materials related to clinical research

You have the option to view materials related to the research plans and methods. If you wish to do
so, please contact your doctor or the Certified Clinical Research Review Board. Please note that you may be required to present your driver's license or another form of identification to verify your identity, and there may be administrative fees associated with accessing these materials.

11. Protection of privacy

The data collected in this clinical study, including symptoms, test results, and visual analogue scales, will use anonymized personal information. We will handle your information with utmost care and manage it strictly to prevent leaks to the outside. The results of this study may be published at academic conferences and medical journals, but your personal information will not be revealed since it is anonymized. We comply with laws and regulations regarding the protection of personal information, and medical professionals are required to protect your confidentiality.

Those involved in this study, such as hospital staff, monitors and auditors, and members of the Certified Clinical Research Review Committee, may review your medical records to confirm proper conduct of the research. However, they are required to keep confidential what they learn in the course of their work and work in accordance with the Personal Information Protection Law. By signing the consent form for this research, you are considered to have agreed to the viewing of your medical records, etc.

The funders and their affiliates may use your Research Data for publication of research results in scientific journals, research and development, provision of information necessary for the proper use of pharmaceuticals and medical devices, and response to requests from regulatory authorities. However, your privacy will be protected in accordance with applicable laws. Even if you withdraw from the research in the middle, we will use the information obtained so far unless you reject it.

12. Storage and use of information, and storage period
The information you provide will be stored and used for a period of 5 years after the end of the research. The information will only be provided to researchers after undergoing a fair review of the research content and will not be bought or sold. Providing the information will not result in any payment to you. After the retention period has ended, the information will be processed in a way that it cannot be personally identified and will be disposed of.

The information received from this research may be used for new research after receiving proper review from an ethics review committee based on the research content. Details of the research will be published on the website of oral and maxillofacial surgery (https://nara-oms.com). If you do not want your information to be used for any other research, please contact us.

13 Research funding sources, conflicts of interest, and intellectual property rights

This clinical study will be funded by the Nara Medical University Clinical Research Promotion Grant. The principal investigator and co-investigators will disclose any potential conflicts of interest in accordance with the Clinical Trials Act and have received approval from the Certified Clinical Research Review Board. This ensures that any potential conflicts of interest will not pose a risk to you.

Although Medisa New Drug Co., Ltd. is funding this study, the research will not be intentionally biased towards a favorable outcome for the company. The principal investigator and co-investigators have disclosed any conflicts of interest with the company and have been approved by the Certified Clinical Research Review Board.

Any funds paid by Medisa New Drug Co., Ltd. to medical institutions and research physicians will be disclosed on a public website in accordance with the Transparency Guidelines for the Relationship between Corporate Activities and Medical Institutions of the Japan Generic Pharmaceutical Association.
NMU4 (Explanatory documents)

This clinical study has been reviewed by the Accredited Clinical Research Review Committee, and appropriate conflict of interest management has been implemented. The results of the study will be published in a public database registered in advance. When presenting the results in academic journals or conferences, the source of funding will be disclosed to ensure transparency and credibility.

In the event that the results of the study give rise to intellectual property such as patent rights, the intellectual property rights will belong to Nara Medical University.

14. About the cost of clinical research

This clinical study will be conducted using your health insurance, so you will not incur any additional expenses other than those covered by your health insurance. However, if you require treatment for a condition unrelated to the study during the research period, you will be responsible for paying the co-payment as usual under your insurance plan.

Please note that participating in this study may require additional visits and examinations, which may cause inconvenience. To alleviate this burden, we offer a fee reduction of ¥3,000 at the time of obtaining consent and ¥3,000 at the time of the final visit, for a total of ¥6,000. Payment will be made through a cash voucher system.

15. In case of health damage caused by clinical research

This clinical study is scientifically planned and based on previous research, but we have clinical research insurance in case participants experience any side effects or other health hazards caused by this clinical study. If it is determined that a health hazard is caused by participating in this study, the participant will receive compensation according to the payment terms of the insurance policy. In case of any health hazard, the participant should contact their doctor immediately. However, if the participant makes an incorrect report to their doctor, or if the damage is caused by their own gross
negligence or intention, their compensation may be reduced or not available.

16. About the Certified Clinical Research Review Board

This clinical trial has been reviewed and approved by the Certified Clinical Research Review Committee under the Ministry of Health, Labour and Welfare to ensure the protection of human rights, safety, and scientific feasibility of the participants. If you or your representative wish to view materials on the research plans and methods, please contact your doctor or the committee.

Name: Nara Medical University Clinical Research Review Board
Location: 840 Shijo-cho, Kashihara City, Nara Prefecture
(URL) http://www.naramed-u.ac.jp/crb/
Contact: (Tel) 0744-29-8835
(FAX) 0744 - 47 - 2019
(Email) ethics_nara@naramed-u.ac.jp

17. What we want you to protect

During the research period, please inform your doctor if you start taking new medication or change the medication you are currently taking or if you visit another hospital. Also, if you are visiting another hospital, please be aware that we may inform them that you are participating in this study.

In addition, even if you wish to continue the clinical study, your attending physician may decide to discontinue it in the following cases. However, your attending physician will provide you with the best treatment possible:

- When it is found that you do not meet the eligibility criteria for participating in this clinical study
- When a change in treatment is necessary due to the condition of your illness
- When the entire clinical study is discontinued
18. Inquiries about this research

If you have any concerns, questions, or notice any abnormalities related to this clinical research, please do not hesitate to consult your doctor or the consultation desk at any time. Additionally, if you become ill or injured or receive any other medical treatment during the research period, please inform your doctor or the consultation desk.

<table>
<thead>
<tr>
<th>Principal Investigator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research Physician</td>
</tr>
<tr>
<td>contact</td>
</tr>
<tr>
<td>Consultation desk on holidays and at night</td>
</tr>
<tr>
<td>contact</td>
</tr>
</tbody>
</table>

Principal Investigator

Dr. Takahiro Yagyuu

Department of Oral and Maxillofacial Surgery, Nara Medical University Hospital

Phone: 0744-29-8875
Informed Consent Form

To: (Responsible physician of the medical institution)

Clinical Research Topic: A Multicenter Randomized Controlled Study of the Efficacy and Safety of Cepharanthine for Oral Lichen Planus

【Explanation】
☐ Clinical research for which we ask for cooperation
☐ Research Organization for this Research
☐ Reasons for selection for clinical research
  ➢ About your illness
  ➢ About the drugs used in this clinical study
  ➢ Purpose of this clinical study
  ➢ Criteria for Participation in Clinical Studies
  ➢ Methods of clinical research
  ➢ Treatment after the end of clinical research
  ➢ Handling of Results after Completion of Clinical Research
☐ Expected benefits and possible disadvantages
☐ Participation and decline of clinical research
☐ If you want to quit participating in clinical research
☐ There is no disadvantage in refusing to participate in a clinical study or quitting halfway through
☐ Disclosure of Information on Clinical Research
☐ Materials related to clinical research
☐ Protection of privacy
☐ Storage and use of samples and information, and retention period
☐ Research Funding Sources, Conflicts of Interest, Intellectual Property Rights
☐ Inquiries about this research
☐ About the cost of clinical research
☐ Other remedies for your disease
☐ When a health hazard occurs due to clinical research
☐ About the Accredited Clinical Research Review Board
☐ What we want you to protect
☐ Samples and information are provided anonymously to the collaborator.
☐ Even after the completion of the research, samples and information will be stored and anonymized for use in the research.

In participating in this research, I have received sufficient explanations on the above matters, received explanatory documents, and fully understood the contents, etc., and therefore agree to participate in this research. We have confirmed that you can withdraw this consent at any time.

Date of consent: [Year] [Month] [Day]   Patient Name: __________________________ (printed) Gender: ______

Address: ___________________________________________   Date of Birth: [Year] [Month] [Day]

Name of proxy writer: ____________________________ (printed)   Relationship with the patient: ____________
※ If the patient's signature is written by a proxy, please indicate it.
【Signature line of physicians and research collaborators】

We have fully explained the clinical research using explanatory documents regarding the above explanations.

Explanation date: [Year] [Month] [Day]   Affiliation: _______   Name: ______________________ (signature)

Explanation date: [Year] [Month] [Day]   Affiliation: _______   Name: ______________________ (printed)
Informed Consent Form

To: (Responsible physician of the medical institution)

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Explanation date: [Year] [Month] [Day]   Affiliation: ____________ Name: ___________________________ (printed)
Withdrawal of Consent Form

To the responsible physician of the medical institution (______________),

I previously consented to participate in your clinical study, "A Multicenter randomized comparative trial on the efficacy and safety of Cepharanthine® for oral lichen planus". However, I now withdraw my consent to participate in the study.

Date of withdrawal of consent: ___________ (Year/Month/Day)

Patient's signature: _________________

Patient's name (printed): _______________

If signed by proxy:

Proxy's name (printed): _______________

Relationship to the patient: _______________

Confirmation:

Date confirmed: ___________ (Year/Month/Day)

Confirming physician's signature: _______________
Withdrawal of Consent Form

To the responsible physician of the medical institution (_________________),

I previously consented to participate in your clinical study, "A Multicenter randomized comparative trial on the efficacy and safety of Cepharanthine® for oral lichen planus". However, I now withdraw my consent to participate in the study.

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Patient's signature: _______________

Patient's name (printed): _______________

If signed by proxy:

Proxy's name (printed): _______________

Relationship to the patient: _______________

Confirmation:

Date confirmed: ___________ (Year/Month/Day)

Confirming physician's signature: _______________