Department of Ophthalmology & Visual Sciences,
Faculty of Medicine, The Chinese University of Hong Kong

PARTICIPANT INFORMATION SHEET

Subthreshold micropulse yellow (577 nm) laser versus half-dose photodynamic therapy for central serous chorioretinopathy : a randomized controlled pilot study

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Introduction

You have been diagnosed with central serous chorioretinopathy (CSCR). More than half of patients with acute CSCR can have spontaneous resolution. Treatment is indicated in patients with persistent CSCR. Half-dose photodynamic therapy (PDT) is the conventional treatment of CSCR. In this study, we aim to compare the efficacy and safety of half-dose PDT and subthreshold micropulse yellow (577-nm) laser in CSCR. 120 participants will be recruited in this study. 60 participants will be from Prince of Wales Hospital.

Study procedures

If you agree to participate in this study, you will be randomized into the half-dose PDT group or the subthreshold micropulse yellow (577-nm) laser group.

In photodynamic therapy, a light-sensitive medicine called verteporin (Visudyne) is injected into the bloodstream. Laser light is then shone into the eye, which activates the medicine and the abnormal choroidal blood vessels is treated. In micropulse laser, a continuous-wave laser beam is chopped into a train of tiny, repetitive, low energy pulses, to treat the areas of diseased retinal pigment epithelium (RPE), inducing resorption of the subretinal fluid.

Patients and investigators will be masked to the treatment allocation group. In the micropulse laser group, 30 ml normal saline will be infused instead of verteporfin, before application of micropulse laser. After treatment, you need to wear protective spectacles and avoid strong light for 2 days. You will need to attend clinic follow up visits at Prince of Wales Hospital or CUHK Eye Centre at 1, 3, 6, 9 and 12 months after the treatment. Upon follow up, you will you will receive microperimtery and imaging with optical coherence tomography (OCT). Fluorescein angiography (FA) and indocyanine green angiography (ICGA) will be performed for patients with persistent subretinal fluid after the treatment, as decided by the doctors.

Retreatment will be considered if the patients meet two of the three following criteria: decreased visual acuity of at least one line from baseline, presence of subretinal fluid on OCT, and significant leakage on angiography. Patients in the PDT group will be considered for retreatment every 6 months whereas patients in the micropulse laser group will be considered for retreatment every 3 months. Patients who have persistent subretinal fluid after 3 treatments of micropulse laser will receive half-dose photodynamic therapy as rescue therapy, 3 months after the third micropulse laser treatment.

Electronic data will be only saved in physically-secured and password-protected computers in our research office. Refusal to participate or withdrawal at any time will not prejudice normal medical care.

Benefits

You will receive treatment of CSCR with either half-dose photodynamic therapy (PDT) or subthreshold micropulse yellow (577-nm) laser, which are effective treatment for CSCR. There are non-invasive investigations that are standard follow-up routines for all CSCR patients. Performing these investigations may allow better understanding of your retinal and choroidal condition after the treatment.

Risks

Participation in this study would require more frequent assessment and follow up during the study period.

Risks of half dose photodynamic therapy include:

- Temporary visual disturbances (abnormal vision, decreased vision, defects in the visual field).
- Pain, swelling, bleeding, or inflammation at the site where the verteporfin medicine is injected. Some people also experience low back pain related to the injection of the medicine.
- Photosensitivity reactions.
- Permanent visual deterioration may occur in a small proportion of patients.

Visual deterioration associated with subthreshold micropulse yellow (577-nm) laser is rare. Scarring of the macula is uncommon for micropulse laser. Normal saline will be infused before application of micropulse laser. Persistence or recurrence of subretinal fluid can occur after half-dose PDT or micropulse laser. Retreatment will be needed for persistent or recurrent disease.

Optical coherence tomography and microperimetry are non-invasive investigations. FA and ICGA are generally safe investigations, but a minority of patients may have nausea and allergy to contrast with rash or urticaria (<1%). Anaphylactic shock is very rare (<0.01%). You can contact the study coordinators if you have any further queries.

Cost of the study

There will be no charges for the treatments. No monetary reward will be received for participating this study.

Alternative treatments if patient opts for not joining the study

You can opt not to take the allocated treatment and just receive the standard of care.

Expected Duration of Research

1 year

Circumstances under which your participation in the Research will be terminated

The research will be terminated upon voluntary withdrawal from the patient.

Arrangements after termination of study

You will receive the standard of care.

Compensation and Treatment available for study related injury

If you are injured during your participation in this study, the investigator will provide medical treatment or refer you to other treatment. Participants are not giving up any of your legal rights by signing this form.

Confidentiality

Electronic data will be only saved in physically-secured and password-protected computers in our research office. Information from this study will be submitted to the Chinese University of Hong Kong for statistical analysis. Only the overall result will be published and your identity will remain confidential. Records and results of all study investigations can be destroyed on your request in future. By signing a written informed consent form, you are (or your legally acceptable representative is) authorizing the Research Ethics Committee (REC) and the regulatory authority(ies) a direct access to your original medical records for verification of clinical trial procedures and/or data, without violating your confidentiality, to the extent permitted by the applicable laws and regulations.

Under the laws of Hong Kong (in particular the Personal Data (Privacy) Ordinance, Cap 486), you enjoy or may enjoy rights for the protection of the confidentiality of your personal data, such as those regarding the collection, custody, retention, management, control, use (including analysis or comparison), transfer in or out of Hong Kong, non-disclosure, erasure and/or in any way dealing with or disposing of any of your personal data in or for this study. For any query, you should consult the Privacy Commissioner for Privacy Data or his officer (Tel no.: 2827 2827) as to the proper monitoring or supervision of your personal data protection so that your full awareness and understanding of the significance of compliance with the law governing privacy data is assured.

Voluntary Participation / Withdrawal

Your participation in this study is entirely voluntary. You will be updated of new information that may be relevant to your willingness to continue participation in the study. You are allowed as much time as you need to consider participation in this study, or to discuss with your relatives prior to signing the consent. You can call us via the contact telephone number provided on this information sheet when you need help to make your decision. You also can express your wish to participate during future routine clinic visits. You have the right to refuse participation or to withdraw from this study at any time, with no prejudice towards your present or future medical treatments at the Chinese University of Hong Kong or any of the hospitals involved. After signing the consent form, a copy of signed consent form will be given, Even after signing the consent form, you are free to withdraw your consent and discontinue you participation in the study at any time. Once you request to withdraw, all clinical data arising from study investigations will be deleted. The clinical data in the medical records will, however, be retained for future clinical management.

For further information, you can contact:
Study coordinators: Dr. Frank Lai
Telephone no.: 2632 2878

Address: Department of Ophthalmology & Visual Sciences,
Eye centre,
Prince of Wales Hospital, Shatin

If you have any questions about your rights as a patient or about research related injuries, you may contact Joint CUHK-NTEC Clinical Research Ethics Committee
Address: 8/F, Lui Che Woo Clinical Sciences Building,
Prince of Wales Hospital, Shatin, Hong Kong
Telephone no.: 2632 3935

Consent form

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CONSENT FORM

I, _____, hereby consent to participate in the research study of "**Subthreshold micropulse yellow (577 nm) laser versus half-dose photodynamic therapy for central serous chorioretinopathy : a randomized controlled pilot study** ".

I have read the **PATIENT INFORMATION SHEET** and **CONSENT FORM.** The study has been explained to me. I understood all the benefits and the risks associated with this study. I have had opportunities to ask questions and all my questions have been satisfactorily answered. I have received enough information about the study.

By signing this consent form, I agree to be treated by medications and procedures decided by my doctor(s). I certify that all information provided is true and correct. I understand that I am free to withdraw from the study at any time, without having to give a reason for withdrawing, and the withdrawal will not affect my future medical care.

I understand that my identity will be kept confidential. I agree to authorize the Research Ethics Committee (REC) and the regulatory authority(ies) a direct access to your original medical records for verification of clinical trial procedures and/or data, without violating your confidentiality, to the extent permitted by the applicable laws and regulations.

Name of Participant	Signature	Date
Name of Witness	Signature	Date
Name of investigator	Signature	Date