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

# Participant Information Sheet

**Progressive lamina cribrosa deformation – A biomarker for fast progressors in glaucoma?**

Principal Investigator: Prof Leung Kai Shun Christopher

## Introduction and Purpose of Research

You are currently participating "Diagnostic Imaging Assessment in the Evaluation of Glaucomatous Optic Neuropathy and diagnosed with glaucoma " at Hong Kong Eye Hospital and have completed at least 36 months follow up visits. Meanwhile, you are diagnosed with glaucoma. Therefore, you are cordially invited to participate in the study aimed to determine whether IOP reduction in eyes demonstrating observable lamina cribrosa (LC) deformation would have a greater absolute risk reduction of visual field (VF) and retinal nerve fiber layer (RNFL) progression compared with those without progressive LC deformation. This is a 2-year clinical trial with the collaboration of the Department of Ophthalmology & Visual Sciences of the Chinese University of Hong Kong and Hong Kong Eye Hospital.

Please read this information sheet with care and ask any questions you may have about this study. Your questions will be answered. You may consult your family members, friends or family doctor if necessary. If you have any questions or would like to have more information, please consult investigators of this research and decide your participation afterwards. Also, you will be given a signed copy of the consent form and participant information sheet for retention.

## Description of Study design and Procedures

Recruitment:
This study plans to recruit 168 subjects with primary open angle glaucoma have been followed up at least 36 months in "Diagnostic Imaging Assessment in the Evaluation of Glaucomatous Optic Neuropathy and diagnosed with glaucoma " at Hong Kong Eye Hospital. Your examination results under "Diagnostic Imaging Assessment in the Evaluation of Glaucomatous Optic Neuropathy and diagnosed with glaucoma " will be taken reference by study-related personnel.

Phase I (36 Months):
168 consecutive patients with primary open-angle glaucoma (POAG) (patients who have been followed up at least 36 months in ongoing study named as "Diagnostic Imaging Assessment in the Evaluation of Glaucomatous Optic Neuropathy and diagnosed with glaucoma "at Hong Kong Eye Hospital) will be recruited. Eyes with progressive LC deformation detected by SDOCT will be randomized to receive additional IOP lowering treatment or continue the current treatment. For patients without progressive LC deformation, they will be randomized with the same manner. Participants no need to receive extra investigations in Phrase I under this study. As participants

have completed examinations under “Diagnostic Imaging Assessment in the Evaluation of Glaucomatous Optic Neuropathy and diagnosed with glaucoma “ at least 36 months. Recruited participants will enter Phrase II under this study directly.

Phase II (24 months):
After subjects have been followed up at least 36 months under “Diagnostic Imaging Assessment in the Evaluation of Glaucomatous Optic Neuropathy and diagnosed with glaucoma “, participants with LC deformation will be randomized at a ratio of 1:1 to either additional IOP lowering treatment group or continued treatment group. Participants without progressive LC deformation will also be randomized at a ratio of 1:1 in the same manner. After randomization, participants will be followed with SDOCT imaging and perimetry 4-monthly within 24 months.

All participants will undergo the following examinations 4-monthly at Phrase II, including:

1. VA measurement
2. Slit-lamp biomicroscopy for the anterior and posterior segments
3. GAT IOP
4. Blood pressure measurements
5. Dark room indentation gonioscopy with Posner lens
6. Axial length measurement with A-scan biometry
7. Central corneal thickness with ultrasound pachymetry
8. Refraction with Auto-refractor
9. Corneal hysteresis
10. Perimetry
    a. Two Visual Field tests, separated by at least 30 min., will be performed for each eye at the baseline visit.
11. SDOCT imaging

All participants will under dilated fundus examination with color optic disc stereophotography yearly.

Continued treatment group:
Participants will continue to receive the same treatment started before recruitment. Participants reaching any of the end-points, including VF progression, decrease in VA $\geq$ 2 lines, and IOP>30mmHg on 2 consecutive follow-up visits in anytime during the study period will be excluded from the study and receive additional treatment, which is the same as the additional IOP lowering treatment group.

Additional IOP lowering treatment group:
Participants will receive additional treatment after randomization to decrease the baseline IOP in the following order: prostaglandin analogue (PGA, once daily), brimonidine (three times daily), carbonic anhydrase inhibitor (CAI, three times daily). For patients who are already on maximum tolerated medications, SLT will be performed with treatment protocol as described previously (360° for 100 applications) and participant will receive one more additional follow-up visit.

**Potential Benefits**

If you decide to participate in this study, you will receive GAT, perimetry, spectral-domain optical coherence tomography (SDOCT) imaging, and fundus photography which are completely free of charge.

**Potential Risks or Discomfort**
Participation in this study would not expose to additional risk compared to the standard routine clinical management. All the clinical investigations in this study are non-invasive, routinely employed in clinical practice and pose no known medical side effects to the participants.

**Cost of the study**
Within the whole study duration, if SLT is performed, one more additional follow-up is required. All ophthalmic examinations and additional treatments are free of charge. No monetary reward will be received for participating in this study.

**Alternative treatments if patient opts for not joining the study**
Refusal to participate or withdrawal at any time will not prejudice normal medical care. Participants will follow the standard routine clinical management, which does not include the aforementioned additional follow-up visits, examinations, and treatments. The attending ophthalmologist will start treatment in accordance with the participant's situation.

**Expected Duration of Research**
This is a 2-year multicenter clinical trial.

**Circumstances under which your participation in the Research will be terminated**
We reserve the right to terminate your participation in the research project. In the event that any safety concerns are raised during the study or interim results from the study show no further samples are needed, your participation will no longer be required.

**Arrangements after termination of study**
After study completion, your care will terminate at the Chinese University of Hong Kong and be handed back to the public hospitals as required.

**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. You 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 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.

**Further Information**

For further information, you can contact us at the address and telephone below:

Contact person: Prof Christopher Kai Shun Leung

Telephone no. : 3943 5846

Address : University Eye Center, 3/F, Hong Kong Eye Hospital,
147K Argyle Street, Kowloon, Hong Kong

If you have any questions about your rights as a subject,

you may contact Research Ethics Committee (Kowloon Central / Kowloon East)

Telephone no. : 3506 8888

Address : Block S, Queen Elizabeth Hospital, 30 Gascoigne Road, Kowloon

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## INFORMED CONSENT FORM

I _____hereby consent to participate in the research study of **"Progressive lamina cribrosa deformation – A biomarker for fast progressors in glaucoma?**".

I have read the **PARTICIPANT INFORMATION SHEET** and **INFORMED CONSENT FORM.** The study has been explained to me. I understood all the benefits and the risks associated with this study. I am not giving up any of my legal rights by signing this form. I have had opportunities to ask questions and all my questions have been satisfactorily answered. I have received enough information about the study.

If the result of my participation in this study caused any physical injury or feel uncomfortable emotionally, the investigator will treat me or refer me for treatment.

By signing this informed consent form, I certify that all information provided is true and correct. I consent to participate in this study and understand that my participation is voluntary and I have the right to withdraw at any time without having to give a reason for withdrawing and the withdrawal will not affect my present and future medical care.

I ☐ agree / ☐ disagree to be contacted via phone or email to see my interest in participating relevant studies in future.

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 my original medical records for verification of clinical trial procedures and/or data, without violating my confidentiality, to the extent permitted by the applicable laws and regulations.

| Name of Participant (in BLOCK Letter) | Signature | Date |
|---|---|---|
| Name of Impartial Witness (If applicable) (in BLOCK Letter) | Signature | Date |

*If participant is not able to read and write, signature of Impartial witness is mandatory.*

| Name of investigator<br>（in BLOCK Letter） | Signature | Date |
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