Optical Coherence Tomography Angiography Evaluation of Ocular Changes in Patients With Carotid Artery Stenosis

NCT04326842

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Informed consent

Respected subjects:

voluntary participation: we are currently conducting a study on the clinical study programme for assessing ocular blood supply in patients with carotid stenosis using optical coherence tomography blood flow imaging. we invite you to participate in this study. Before you decide whether to participate in the study, please read the following carefully:

(1) Background and purpose of this study

As one of the most energy-consuming tissues in the body, the retina is particularly vulnerable to ischemia. In order to meet the metabolic needs of retinal tissue, the arteriovenous bifurcation of the retinal arteriovenous arterioles and venules form several interconnected retinal vascular plexus. OCTA can directly see the retinal vascular system, which provides an easy window for monitoring vascular and circulatory functions. an increasing number of studies have shown that abnormal retinal microvascular features can be used as a novel biomarker that reflects the severity of underlying cardiovascular, neurodegenerative and microvascular diseases. Because the blood flowing to the retina is mainly supplied by the internal carotid artery (ICA), we speculate that the changes of retinal microvessels after carotid stenosis may reflect the disease state or therapeutic effect of patients with carotid stenosis.

(2) Research observation procedures and duration

we will conduct a full ophthalmic examination of you 1-2 days before and 4-5 weeks after surgery, including Snellen best corrected visual acuity (BCVA), slit lamp biomicroscopy, OCTA、 color fundus photography and indirect ophthalmoscopy, if you are willing to participate in this study. The carotid artery color Doppler ultrasound or 64 layers CT cervical vessels were performed 4~5 weeks after

operation. and give corresponding guidance to your eye health management according to your examination results.

(3) Who should not participate in the study?

If you have glaucoma, retinopathy, optic neuropathy, uveitis, ocular trauma, or have undergone intraocular surgery (except for non-complex cataract surgery), you are not covered by this study.

(4) Possible benefits and risks of participation in research

Benefits: To participate in this study, you can obtain multiple comprehensive ophthalmic examinations, and we will give appropriate guidance to your eye health management based on your examination results.

Risk and compensation: This trial was mainly assessed by ophthalmological examination, which involved no trauma and no risk

(5) Your rights

your participation in this study is completely free and voluntary, and if you decide to participate, you need to sign written informed consent, but during the course of the study, you may withdraw at any time without reason, and the same physician who conducted the study will also decide to let you out if it is not in your best interest to continue your participation in the study.

(6) Confidentiality

to the extent permitted by law, all information and inspection results collected in this study about you will be strictly confidential. will not be provided to any other person and unit other than the research physician. All your research records and test results are limited to the hospital superior department management department, ethics committee members and research doctors analysis processing and verification, they will strictly keep your secret. Signing this document indicates that you have authorized the use of your above medical records by the applicant or researcher for the purpose of participating in this scientific research.

(7) Processing of medical data

Because the original data belong to outpatient or inpatient medical information, unified by the medical records room in accordance with national laws and regulations custody and destruction.

(8) Voluntary abandonment of specimens or surgical waste by patients

No.

(9) Is there a need for payment?

to compensate for the inconvenience that your participation in this study may cause you, this study will provide free eye examination (including visual acuity examination, OCTA 、 vision slit lamp, fundus photography, indirect ophthalmoscope) without your payment.

If you combine the treatment and examination required for other diseases at the same time, and the cost of switching to other treatments because the treatment is ineffective, it will not be covered free of charge.

(10) Contact information for additional information or assistance

During the study, you can always know the relevant information, if you have any questions about the study, please contact

Researcher Shek Yeon, Tel :18646 1277 88

Zhu Shiyi Contact telephone number 13263500305

Subject states:

i have read the above informed consent in detail. for this study has been satisfactorily explained, i understand the purpose of the study, the research steps and the possible benefits and risks of participating in the study after i am willing to participate in the study and cooperate fully with the researchers.

Subjects' signatures:_____Date:_____ Year_____Month_____Day

Contact number:_____ Mobile number:_____

Signature of subject/legal guardian_____ Date:_____ Year_____Month

Day

Subject/legal guardian contact number_____

Doctor's statement:

i confirm that the details of this study have been explained to patients, especially the risks and benefits that may arise from participating in this study. at the same time ensure that the medical information collected in this study is only used in this study.

_Doctor's signature:_____ Year_____Month_____Day

_Doctor's telephone number :1870 4616237 13263500305 Mobile Number :18646127788

Signature of researcher_____ Date:_____ Year_____Month Day

the details of this study have been reviewed by the ethics committee of the first affiliated hospital of harbin medical university. both the research center and you will retain 1" informed consent "you have signed.

Thank you for participating in this clinical study

Contact number :0451-85552350