Version number: 20210420.2

Notes of Informed Consent Form

Practice Name: A Randomized, Controlled, Multi-centre Clinical Study on the Effectiveness and Safety of Low-Intensity Single-wavelength Red Light in Controlling High Myopia in Children and Adolescents

Research Institution: Shanghai First People's Hospital/ Shanghai Ophthalmopathy Prevention & Treatment Centre

Cooperative Institutions: Children's Hospital of Soochow University
Xinhua Hospital Affiliated to Shanghai Jiaotong University School of Medicine
Shanghai East Hospital South Branch
The Children's Hospital Zhejiang University School of Medicine
Shanxi Eye Hospital

We are glad to invite you to join in a practice of a randomized, controlled, multi-centre clinical study on the effectiveness and safety of low-intensity single-wavelength red light in controlling high myopia in children and adolescents. Before deciding to participate in this practice, please reading the informed consent form carefully. If you have any questions, you can ask the researchers or members of the clinical practice team to explain the terms and information which you do not understand.

1. Background and Purpose

1.1 Background

At present, the number of myopic children is increasing. Myopia not only affects children's study, but high myopia also affects the health of children's eyes. The low-intensity single-wavelength red light instrument has been on the market for many years. It is a safe ophthalmology instrument. In the preliminary exploratory testing, we found

this instrument could control myopia. Therefore, ophthalmologists from six hospitals need to further observe this instrument.

1.2 Purpose

To observe the effectiveness and safety of the low-intensity single-wavelength red light in controlling high myopia in children and adolescents.

2. Methods

2.1 Who can join in the practice?

1) Age 3-16 years old (including 3 years old and 16 years old), boy or girl;

2) Clinical diagnosis confirms that myopia has occurred in at least one eye;

3) The guardian and patient (or signed by the guardian) voluntarily sign the "Subject Informed Consent".

2.2 Who cannot join in the practice?

Patients with the following symptoms will not be able to participate in this trial:

1) A history of photosensitivity, glaucoma, glaucoma syndrome, ocular hypertension, and macular disease or damage in the fundus;

2) Corneal curvature examination, the average K value of the anterior surface of the cornea is ≥45;

3) Patients with systemic diseases such as heart, liver, kidney, and congenital hereditary myopia;

4) Patients with chronic eye diseases such as eye trauma and oblique or surgical eye, atopic keratoconjunctivitis;

5) People who have had other eye diseases such as inverted trichiasis, severe corneal and conjunctival infections in the past;

6) Those with neurological diseases and allergies or contraindications to atropine drugs or other therapeutic drugs;

7) Patients with immune system and systemic diseases such as albinism, psoriasis, nephrotic syndrome, systemic lupus erythematosus, diabetes, etc.;

8) People with epilepsy and mental disorders who cannot communicate normally;

9) Those who have previously received other treatments to control the development of myopia, such as the use of anticholinergic drugs such as atropine within 3 months, or have participated in other functional frame mirrors, multifocal soft mirrors and other related researchers;

10) Other situations judged by the researcher to be unsuitable for participating in the research.

2.3 Research Methods

This research will be conducted in 6 research centres across the country. A total of 190 subjects will participate in this study. Among them, the centre plans to recruit 32 subjects.

Approximately 32 subjects will be recruited in this study for scientific, regulatory, and ethical reasons. Therefore, if you have recruited this target number of subjects and you are still in the screening period, you may not be included.

From the date of signing the informed consent form, it is estimated that each subject will participate in the study for 365 to 379 days.

The trial is divided into three periods: screening period, enrollment and randomization period, and treatment period.

Screening period: from the date of signing the informed consent to the issuance of the instrument, the main purpose is to improve the relevant inspections to confirm that you are suitable for inclusion in the group.

Enrollment and randomization: After confirming that you are suitable for enrollment, and you also agree to randomly assign the test group and the control group, the research doctor will open the random card to confirm your specific grouping and different plans according to different groups so that you can start treatment.

Treatment period: 5 visits to the hospital are required to observe the effectiveness and safety of the treatment.

3. Risks and Benefits

3.1 Risks

Currently, no known risks are reported in this test instrument.

Unknown risk: Your child may experience side effects or discomfort that are not listed in this consent form. This may include the deterioration of your child (illness). Some side effects may not be known. If your child experiences any side effects or discomfort, please contact the doctor or research staff immediately.

3.2 Benefits

If you agree to participate in this study, your child will likely receive direct medical benefits, including:

1) During the practice period, members of the intervention group used low-intensity single-wavelength red light instruments for treatment for free.

2) After one year of observation in this study, if the test results prove that the interventional treatment of the intervention group is safe and effective, the sponsor promises to provide control group members with free low-intensity single-wavelength red light treatment for one year after the study is over.

3) The control group and the intervention group are free of charge for all related inspections during the study period and provide 100 yuan transportation fee for each visit.

4) After treatment, patients may effectively prevent and control myopia.

5) During the study period, glasses for the control group and intervention group are free.

6) Help researchers to observe the effectiveness and safety of low-intensity single-wavelength red light for myopia control, and make contributions to the field of children's myopia treatment.

4. Your Rights

You have the right to decide whether to participate in this practice. If you cannot make decisions immediately, you have sufficient time to consider it. If necessary, you can make decisions after discussing it with your relatives, friends, etc. whom you trust. If you decide not to participate in this practice, your relationship with the investigator and sponsor will not be affected, you will not be discriminated against or retaliated, and your treatment and rights will not be affected. If you decide to participate in this practice, we hope you can complete the trial if there is no special reason, but you have the right to withdraw at any time during the practice. If you decide to withdraw, please tell the investigator in time.

During the practice, you can learn about the information related to you in this practice at any time.

5. Privacy Protection

The personal information you provide to the researcher (such as name, gender, contact information, questionnaire, etc.), not only be used to the normal research, but may also be obtained to the following persons or institutions:

- The staff (inspectors, auditors, etc.) of the research funding agency related to this experiment;
- National and local Food and Drug Administration and other administrative agencies.

However, no one can disclose your personal information to others or other institutions without your permission. Except for researchers and administrative agencies, no other person or organization has the right to contact you on the initiative of this trial, or provide you with information about this experiment directly.

The results of this experiment may be published in the form of academic papers, but your personal information will not appear in any publicly published documents.

6. Withdraw from research

In the following situations, for your child's health, the researcher may withdraw you from this practice without your consent:

- If your child continues to participate in this practice, his/her risk may outweigh his/her benefit;
- Your child did not participate in the practice in accordance with the research plan in accordance with the instructions of the investigator;
- The test is terminated early.

8. Compensation for the Injury Caused by the Experiment

If your child feels unwell during the practice, please tell your guardian in time. Your guardian will contact your research doctor, and the doctor will provide you with appropriate medical treatment. If your child's injury is directly caused by participating in this trial, you do not have to bear the medical expenses incurred due to medical treatment, and this part of the expenses will be borne by the trial sponsor.

9. Other Options for Diagnosis and Treatment

You do not have to participate in this study to get help for your child's illness. For the treatment of your child's myopia, alternative options in this study may include the use of atropine, orthokeratology and other treatments. Your research doctor can discuss the risks and advantages of these alternative treatment options with you.

10. Research Expenses

The investigator will pay the costs of glasses, examinations and treatments during your child’s participation in this practice. Other medical expenses not related to this trial will be paid by you or your medical insurance.

Contact:

1. Office of Medical Ethics Committee of Shanghai First People's Hospital
Phone Number: 021-36123569

2. Researcher: Yan Xu
Phone Number: 18621080996

This informed consent form is in duplicate. The investigator and you keep one copy each.

[The following is the signed page of informed consent]

Informed Consent

Agree to declare:

1. I have carefully read the instructions to the subjects and understand the relevant background of this experiment. The investigator has explained the characteristics of the study and possible adverse reactions to me in detail, and answered my questions.

2. I know that if I refuse to participate in this practice, my benefits and rights will not be affected. After understanding all the contents of the subject's instructions and after full consideration, I voluntarily participate in this practice.

3. I am willing to follow the instructions of the investigator and participate in the experiment in accordance with the research plan. During the practice, I have the right to withdraw at any time. I need to tell the researcher in time before I withdraw.

4. During the experiment, if there are any symptoms of discomfort, I will tell the investigator in time.

Signature of Subject:

Name (in regular script) Sign Date of Signature

Signature of Subject's Agent/Guardian:

Reasons why the subject could not sign this page:

The relationship between the agent/guardian and the subject:

Name (in regular script) Sign Date of Signature

Signature of Investigator:

Name (in regular script) Sign Date of Signature