Informed Consent Form - Informational Page

Dear Little Friend

Hello!

You will be invited to participate in a study of the efficacy and safety of auricular pressure pills to reduce rebound phenomenon after discontinuing 0.01% atropine eye drops in children with myopia: a three-arm, blinded, randomized controlled trial.

This informed consent form is to tell you about the purpose of the study, what you will be asked to do while the study is being conducted, the possible benefits you may get and the possible risks you may have, etc. You can read it carefully and talk to your parents (mom, dad, or any other person in your family) before you make a decision, and after you take part in the study you can withdraw from the study at any time if you change your mind, and your doctor will be of the greatest help to you whether or not you take part in the study.

I. Background and Purpose of the Study

At present, the incidence of myopia among children and adolescents in China remains high and ranks first in the world, and the occurrence of myopia shows a low age, which means that there will be a large number of myopia and high myopia patients in China in the future. The visual damage caused by myopia, especially high myopia, is irreversible and seriously jeopardizes the overall quality of China's nationals. Therefore, the prevention and control of myopia in children and adolescents has become one of the most important national policies of our country. Therefore, we invite you to participate in the project "Efficacy and safety of auricular acupressure pills to reduce rebound phenomenon after discontinuing 0.01% atropine eye drops in children with myopia: a three-arm, blinded randomized controlled trial study ". The purpose of this study is for the effectiveness and safety of auricular pressure pills to reduce rebound response after stopping atropine in myopic children.

II、Things you need to cooperate with to participate in the study

This study is expected to last for 2 hours. If you take part in this study, you will first be screened to see if you meet all the requirements to take part in this study. After screening, you will receive ear acupuncture and 0.01% atropine treatment.

1. Before you are enrolled in the study, you will undergo the following examinations to determine whether you can participate in the study:

The doctor will ask and record your medical history, clinical signs and symptoms, medications you are using and have used in the past, and perform examinations such as visual acuity, intraocular pressure, eye axis, medical optometry after dilating the pupils, and fundus images. All of the above examinations are free of charge and will not adversely affect your health or condition.

2. If your above screening meets the inclusion criteria, the study will be conducted according to the following steps:

(1) If you are included in the criteria, during the trial period, you will be provided with unified guidance on hygienic eye use, which will be formulated with reference to the Implementation Plan for Comprehensive Prevention and Control of Myopia in Children and Adolescents, which was jointly issued by the Ministry of Education, the National Health Health Commission and other 8 departments in 2018.

(2) Your doctor will decide which group of treatment you will receive based on the principle of randomized controlled studies. Atropine gradual discontinuation group: 0.01% atropine eye drops will be given by the gradual reduction method (Shenyang Xingqi Ophthalmic Pharmaceutical Co., Ltd., Shenyang, China, State Drug Administration License No. H20243320,0.04 mg) to reduce the dose by 1 day per month, and ultimately reduce the atropine treatment from 7 days per week to complete discontinuation in 6 months, with a follow up of 6 months. Auricular pressure point group: AA therapy will be added to the 0.01% atropine drops tapering method. Auricular points: shenmen (TF4), heart (CO15), liver (CO12) spleen (CO13),

kidney (CO10) and eye (LO5). The acupuncturist first probes the auricular points with a metal probe and asks the patient if he or she has any "qi" sensations, such as warmth, numbness, distension, or pain. After confirming the auricular points, the ear is cleaned with a 75% ethanol solution and dried with a sterile, dry cotton ball. After that, the acupuncturist will fix the ear with the left hand and use the right hand as tweezers to place the tape (10 × 10 mm) containing Wang Bu Liuhang seeds (Wujiang Jia Chen Acupuncture and Moxibustion Instrument Co., Ltd., Suzhou, China) onto the selected auricular area. One side of the auricle was treated first, then the tape was left in place for 5 days, on day 6 the tape would be removed and rested for 2 days, and on day 8 a new tape would be placed on the other side of the ear. Replacement of the tape is intended to minimize adverse events (AEs) that may result from unilateral prolonged stimulation. Additionally, participants will be told to self-administer 15-20 strokes of vertical, appropriate pressure on the Wang Buerhoff seed for sensation, for a duration of 4 to 5 times per day. The treatment process will last for 18 months with a follow-up after 6 months. Sham Auricular Acupuncture Group: the acupuncturist will apply skin-colored tape without Wang Bu Liu Xing seeds to the auricular acupoints through the 0.01% atropine drops tapering method used in the control group; no massage or acupressure will be received during the course of the treatment at. the SAA's referenced an earlier study. At the end of the study, patients in the SAA group will receive compensatory AA treatment with the same protocol as the AA group

(3) Atropine treatment will continue for 12 months, with a 6-month reduction, and subsequent follow-up after discontinuation will continue for 6 months.

(4) The following examinations will be conducted every 3 months: naked eye visual acuity, refraction, eye axis, corneal curvature, anterior chamber depth, and the following examinations will be conducted every 6 months: choroidal thickness, choroidal vascular index, and choroidal perfusion examination. You are required to truthfully reflect any changes in your medical condition to the doctor, who will collect your medical history and conduct the necessary examinations.

3. Other matters requiring your cooperation

You should come to the hospital at the follow-up appointment agreed between the doctor and you. Your follow-up visits are very important because the doctor will determine whether the treatment you are receiving is really working and will give you timely instructions.

III、 What are the inclusion and exclusion criteria?

1.1 Inclusion criteria

1. Fulfillment of the diagnostic criteria for myopia; and
2. Age 6-12 years old, male or female.
3. Spherical lenses of -1.00 to -4.00D (astigmatism ≤1.50D, refractive error ≤1.50D) in one or both eyes.
4. Best corrected distance visual acuity of 0.20 logMAR or better in both eyes.
5. Intraocular pressure (IOP) less than 21 mmHg.
6. Informed consent has been signed by the guardian and participation is voluntary.

1.2 Exclusion Criteria

Patients who fulfill any of the following criteria will not be allowed to participate in the study:

1. Ocular diseases other than refractive errors (e.g., strabismus, amblyopia, keratitis, glaucoma, cataract, retinal detachment, etc.);
2. Those with systemic conditions that may affect refractive development (e.g., Down syndrome, Marfan syndrome);
3. Patients with uncontrolled systemic or debilitating diseases and immunodeficiencies, combined with severe primary diseases of the cardiovascular, hepatic, renal and hematopoietic systems, immune system disorders, and psychiatric disorders;
4. Allergic individuals with hypersensitivity to multiple medications;
5. Those undergoing eye surgery 4 weeks prior to screening;
6. Those who are scheduled to undergo eye surgery within 1 year of enrollment;

7. Those who have participated in a clinical study of another drug within 3 months prior to screening;

Patients who are unable to cooperate with treatment, observation and evaluation.

IV. What are the benefits if I participate in this study?

First, you will receive more comprehensive and accurate eye testing and evaluation. You will have a better understanding of the development of myopia in children and adolescents. Secondly, all subjects will be given monthly eye hygiene surveys and instructions to minimize the risk factors for myopia, which will help to slow down the progression of myopia. In addition to the fact that there will be no direct benefit from participating in this study, the acquisition of information from this study may help physicians and researchers to further confirm the role of auricular pressure pills in reducing the rebound effect of discontinuing atropine in children with myopia, for use in other patients with similar conditions. Your participation will help us develop more effective treatment options and methods that may be helpful to people facing similar health problems in the future.

Ⅴ. What are the risks of my participation in the study?

Although preliminary studies have shown that ear acupuncture and 0.01% atropine are relatively safe, all treatment methods may cause side effects. For auricular pressure pills, there may be adverse reactions such as allergy to the adhesive tape and pain in the skin where the auricular pressure points are applied; 0.01% atropine eye drops may have adverse reactions such as unstable intraocular pressure, photophobia, dryness of the eyes, and blurred vision. There is no guarantee that the above interventions will definitely work for you. If you experience any discomfort, new changes in your condition, or any unforeseen circumstances during the study, whether or not they are related to the above treatments, you should notify your doctor, who will make a judgment and medical treatment for this. You will need to follow up with the hospital on time during the study for some tests, which may cause you trouble or inconvenience.

VI. If you do not participate in this study, are there other alternative tests/evaluations/treatments and what are the advantages and disadvantages of each (containing this program)

Your study doctor will discuss with you the other treatment options currently available for your condition, including the corresponding risks and benefits. Currently, multifocal soft contact lenses and RGP are available to slow myopia progression, which are relatively effective, but need to be worn in contact with the cornea throughout the day, with high care requirements, as well as corneal damage as a side effect.

VII. What are my medical expenses for participating in this study?

The research group (Ningbo Eye Hospital) will pay for all study-related examinations (including routine eye examinations, visual acuity, refraction, axial length, corneal curvature, anterior chamber depth, choroidal thickness) and all treatments (auricular acupressure pills, 0.01% atropine eye drops) during your participation in this study.

The physician will make every effort to prevent and treat any harm that may occur as a result of this study. If adverse events occur during clinical trials, a committee of medical experts will determine whether they are related to ear acupuncture and the 0.01% treatment method. In the event of adverse reactions and injuries caused by the above treatments or diagnostic tests and treatments required by the study protocol, the group will pay for the relevant treatment costs and financial compensation in accordance with China's Code of Practice for the Quality Management of Drug Clinical Trials.

If you also combine the treatment and examination required by other diseases, it will not be included in the free scope.

VIII. Can I be compensated for participating in this study?

You will not be paid for participating in this study.

IX. Compensation for Damages

The study doctors and Ningbo Eye Hospital will make every effort to prevent possible harm due to this study. In the event of study-related damages, upon identification, appropriate and reasonable compensation will be paid in accordance with local Chinese laws and regulations.

X. Is personal information confidential?

We take the protection of your privacy and personal information very seriously. All personal information collected in this study will be kept strictly confidential and will be used only for the scientific purposes of this study. All personal data we collect, including your health information, contact information, etc., will be de-identified and anonymized. Your information will be securely stored in a password-protected database that is accessible only to authorized researchers. Paper records will be stored in locked filing cabinets and managed only by the research team leader. Only members of the research team directly involved in this study will have access to your information. No information that could identify you will be disclosed when the results of the study are published. Data provided in any public reports and publications will be aggregated and anonymized.

If you decide to withdraw from the study, we will stop collecting new information about you. Information already collected will continue to be treated confidentially and used in accordance with the research protocol and data protection legislation. Your personal information will be kept for at least five years after the completion of the study, in accordance with relevant legislation and institutional policy. Thereafter, all information will be securely destroyed or permanently anonymized. If you have any questions about the use or protection of your personal information, or would like further information about how your information will be handled, please do not hesitate to contact our research team.

XI. Do I have to take part in this study?

Please understand that your decision to take part in this study is based entirely on a voluntary personal decision. You have complete freedom to choose whether or not to participate, and your decision will not affect any standard medical care you receive now or in the future. Before deciding whether or not to participate, you are encouraged to give it full consideration and discuss it with your family, friends or medical advisor. If you have any questions or concerns, our research team is ready to

help and answer them.

There is no compulsion for you to join this study, and if you choose not to participate, there will be no negative impact on your medical care or relationship with your healthcare provider. If you decide to participate but change your mind at any stage of the study, you have the full right to withdraw without having to give any reason and withdrawal will not negatively affect your medical care. If you choose not to participate, we will continue to provide you with standard medical care and can provide you with more information about these alternative options.

We respect every decision you make and thank you for considering participation in this study.

XII. Who should I contact if I have questions or problems?

If you have any problems, questions, or difficulties participating in this study, we encourage you to contact our research team. Our team is always ready to help and support.

Primary contact:

Research Coordinator:

Contact phone number:

Email:

Contact hours: week [Monday] to week [Sunday], [8] a.m. to [5] p.m.

Alternate Contact:

Principal Investigator:

Contact Tel:

Email:

Emergencies:

In case of emergency, please call the hospital's emergency contact number directly at [hospital emergency contact number] or go to the nearest emergency room.

Ethics Committee Contact Information:

You may also contact the Ethics Committee if you have any concerns about your right to participate in the study or the conduct of the study.

Ethics Committee Contact Number: 0574-87862233

Address: No. 599, Beiming Cheng Road, Yinzhou District, Ningbo, China

XIII. Acknowledgments

Clinical research is indispensable for the development and progress of medical science, and your participation will contribute to the progress of medical science. As the researcher and sponsor of this study, we will always keep your contribution in mind and express our sincerest gratitude to you!

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Research Participant Statement:

I have read the above informed consent form or it has been explained to me verbatim.

I have been given the opportunity to ask questions about the study and all of my questions have been answered to my satisfaction.

I understand that my participation is completely voluntary and that I may withdraw from the study at any time without any adverse effects.

I understand the purpose, procedures, and possible risks and benefits of this study.

I agree that my personal medical information will be used for research purposes in a confidential manner.

I choose to [accept / not accept] participation in this study.

Participant Signature:

Name (printed): _____

Signature: _____

Date: _____

Signature of legal guardian or authorized representative, if applicable:

Name (print): _____

Signature: _____

Date: _____

Relationship with participants: _____

Research team statement:

_____

_____

I confirm that I have explained all relevant information about the study to the participant and answered all of the participant's questions. I am confident that the participant fully understands what their participation means.

Name of study coordinator/researcher (print): _____

Signature: _____

Date: _____