Exploring Paraspinal Electromyographic Features in Adolescent Idiopathic Scoliosis Patients

Informed Consent - Informed Communication Page

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Dear Patient:

You have been diagnosed with Adolescent idiopathic scoliosis (AIS).

We would like to invite you to participate in a pilot study, Exploring Paraspinal Electromyographic Features in Adolescent Idiopathic Scoliosis Patients. We will use high-density surface electromyography (HD-sEMG) to comprehensively analyze the differences between paravertebral muscles on the concave side of the parietal vertebrae in AIS patients with side bending, in addition to comparing the electromyographic signals of AIS patients with those of the healthy population, to further discover the characteristic differences in the electromyographic signals of the paravertebral muscles in AIS.

Before you decide whether or not to take part in this study, please read the following as carefully as possible. It will help you to understand the study and why it is being carried out, the procedures and duration of the study, the benefits, risks and discomforts that may be available to you if you take part in the study. If you wish, you can also discuss it with your relatives and friends or ask your doctor to explain it to you to help you make your decision.

Study Introduction

I. Background and purpose of the study

Adolescent Idiopathic Scoliosis (AIS) is a three-dimensional deformity of the spine that occurs between the ages of 10 and early 18 years, and is one of the most common deformity conditions in the adolescent musculoskeletal system. It is clinically characterized by spinal scoliosis in the coronal plane, sagittal imbalance and horizontal rotation. Epidemiologic surveys have shown that the global prevalence of AIS ranges from

0.47% to 12%; the prevalence of AIS among primary and secondary school students in China ranges from 0.11% to 5.14%, with an increasing trend.

Lack of accurate progression risk prediction is a major cause of poor outcomes and high surgical rates in AIS. As a chronic insidious disease, AIS may present as a mild spinal deformity in early adolescence; approximately 60% of adolescent patients will continue to progress, and 30% of these may develop a severe scoliosis deformity. Improving muscle imbalances on either side of the scoliosis has been shown to have a significant effect in halting scoliosis progression. Based on the important role of paravertebral muscles in clinical evaluation, there is an urgent need to develop an efficient non-radiation assessment method for a more comprehensive understanding of paravertebral muscle status in order to more accurately assess the scoliosis status and avoid unnecessary radiation exposure.In this study, we will investigate whether the paraspinal muscle electromyographic signals are specifically altered in patients with AIS and analyze their characteristics in comparison to a healthy population. The Ethics Committee has considered the study to be medically ethical in accordance with the principles of the Declaration of Helsinki.

II. Who should not participate in the study

① Subjects with previous spine-related diseases such as ankylosing spondylitis, spinal neurofibroma, spinal tuberculosis, spinal trauma and so on;

② Subjects with a combination of serious medical diseases and psychiatric patients;

③ Those with ECOG score > 2, which may have an impact on the study results;

④ Those who are affected by external factors such as economy and individualized differences so that they are unable to complete the study.

III. What you will need to do if you participate in the study

1. Before you are enrolled in the study, he/she will undergo the following tests to determine if you can participate in the study:

Your doctor will ask for and take a medical history and perform a physical examination.

You will have imaging tests (x-rays).

2. If you have completed the above tests, the following steps will be taken to conduct the study

The doctor will take information about you, including SAGA 64-channel high-density surface EMG signals, demographic information, and Cobb.

IV. Possible benefits of participating in the study

You and the community will likely benefit from this study. Such benefits include a clearer understanding of your own disease condition and the possibility that this study may help to establish a new treatment protocol for AIS that can be used for other patients with similar conditions.

You will receive excellent medical care during the study, with priority registration and free consultations.

V. Possible Adverse Effects, Risks and Discomfort, Inconvenience of Participating in the Study

Although no adverse reactions to the study methodology have been identified to date, if you experience any discomfort, a new change in your condition, or any unforeseen circumstances during the study, whether or not related to the treatment, you should promptly notify your physician, who will make a judgment call and provide medical treatment.

The physicians and the research team will make every effort to prevent and treat any harm that may occur as a result of this study. If an adverse event occurs during the clinical study, the governmental administration of the research project and the ethics committee of the hospital will determine whether it is related to the study.

The investigator/subject group will pay for the cost of treatment and financial compensation for study-related damages.

You will be required to follow up at the hospital on time and do some physical and chemical tests during the study, which may cause you trouble or inconvenience.

VI.Costs

Physical and chemical tests during the study are free of charge, but not if you have other medical conditions that require treatment or tests.

VII. Is personal information confidential?

Your medical records (study charts/checklists, etc.) will be kept intact at the hospital, and your doctor will record the results of the tests on your outpatient medical record. The researcher or members of the subject group, the ethics committee and the government department to which the subject belongs will be allowed to access your medical records. Any public reporting of the results of this study will not disclose your personal identity. Every effort will be made to protect the privacy of your personal medical information to the extent permitted by law.

It is possible that your medical records and examination specimens may be utilized again in future studies other than this study. You may also state now that you refuse to have your medical records and specimens utilized in studies other than this study.

VIII. How can I get more information?

You may ask any questions about this study at any time. Your doctor will leave you his/her phone number to be able to answer your questions.

If you have any complaints about your participation in the study, please contact the hospital ethics committee office.

Your doctor will keep you informed if there is any important new information during the course of the study that may affect your willingness to continue participating in the study.

IX. You may voluntarily choose to participate in the study and withdraw from the study.

Participation in the study is entirely voluntary. You may refuse to participate in this study or withdraw from the study at any time during the study without affecting your relationship with your doctor and without prejudice to any loss of medical or other benefits to you.

Your participation in this study may be discontinued at any time by your doctor or the investigator in the best interest of you.

You may not participate in this study or you may choose to withdraw from the study in the middle of the study.

If you withdraw from the study for any reason, you may be asked about your treatment. You may also be asked to have laboratory tests and a physical examination if your doctor thinks it is necessary. This is very beneficial to protect your health.

X. What should I do now?

It is up to you to decide whether or not to take part in this study. You can discuss your decision with your family or friends.Before you make the decision to participate in the study, please ask your doctor as many questions as possible until you fully understand the study.Thank you for reading the above material.If you decide to take part in this study, please let your doctor or research assistant know and he/she will arrange everything for you about the study.Please keep this material with you.

Informed Consent - Consent Signature Page

Clinical research project name: Exploring Paraspinal Electromyographic Features in Adolescent Idiopathic Scoliosis Patients.

Clinical research unit: The First Affiliated Hospital of Zhejiang University of Traditional Chinese Medicine.

Ethical Review Approval No.: Upper right corner of the ethical review approval document.

Statement of Consent

I have read the above description of this study and have had the opportunity to discuss and ask questions about this study with my physician. All the questions I have asked have been answered to my satisfaction.

I am aware of the possible risks and benefits of participating in this study. I understand that participation in the study is voluntary and I confirm that I have had sufficient time to consider this and understand it:

① I can ask my doctor for more information at any time.

② I can withdraw from this study at any time without discrimination or retaliation, and my medical treatment and rights will not be affected.

I am equally aware that if I withdraw from the study in the middle of the study, it would be very beneficial to me and to the study as a whole if I tell my doctor about any changes in my condition and complete the appropriate physical and physical-chemical examinations.

I give my consent for the ethics committee or sponsor's representative and the research quality inspector to have access to my research data.

I agree□ or refuse□ to have my medical records and pathology specimens utilized for research other than this study.

I will be given a signed and dated copy of the informed consent form.

Finally, I have decided to agree to participate in this study.

Subject's signature:__ __ __ ____ __ Date__ __ __ ____ __

Subject contact number: __ __ __ ____ __ Cell phone number: __ __ __ ____ __

Signature of legal representative (if any): __ __ __ ____ __ Date__ __ __ ____ __

I confirm that I have explained the details of this study to the patient, including his/her rights and possible benefits and risks, and given him/her a copy of the signed informed consent form.

Signature of researcher:： __ __ __ ____ __ Date__ __ __ ____ __

Researcher's work phone number：__ __ __ ____ __ Cell phone number: __ __ __ ____

Contact number of the Ethics Committee Office of the First Affiliated Hospital of Zhejiang University of Traditional Chinese Medicine:

0571-87072953/87013311