A multicenter, prospective, observational real-world study evaluating the efficacy and safety of Aximexine sustained-release capsules in the treatment of active axial spondyloarthritis (axSpA)

Informed Consent Form

Version number: 2.0

Version date: March 5th, 2026

Screening number：|__||__|-|__||__| **Patient name abbreviation：**|__|__|__||__|

Dear patient:

Hello! We will invite you to participate in a multicenter, prospective, observational real-world study initiated by researchers to evaluate the efficacy and safety of Aximexine Extended Release Capsules in the treatment of active axial spondyloarthritis (axSpA). This study is a multicenter, prospective, observational clinical research project with study number CSPC-GSS-axSpA-001. This research proposal has been reviewed and approved by the Ethics Committee of the Chinese People's Liberation Army General Hospital.

Before deciding whether to participate in this study, please read the following content as carefully as possible. It can help you understand the research and why it is necessary to conduct it, the procedures and duration of the research, and the potential benefits, risks, and discomforts that may arise from participating in the research. Please take some time to carefully read the following content. If you have any unclear questions or terminology, you can discuss with the relevant physician.

I、Research background

Axial spondyloarthritis (axSpA) is a chronic inflammatory disease that mainly affects the axial skeleton, characterized by inflammatory lower back pain, morning stiffness, attachment point inflammation, and arthritis. It can also be accompanied by extraarticular manifestations such as uveitis and psoriasis. In terms of treatment, nonsteroidal anti-inflammatory drugs (NSAIDs) such as diclofenac, celecoxib, and acesulfamethoxazole are recommended as first-line drugs for axSpA treatment by clinical practice guidelines both domestically and internationally.

Asimexin is a derivative of indole-3-acetic acid, mainly due to its metabolite indomethacin exerting pharmacological activity. Like other anti-inflammatory drugs, it has anti-inflammatory, analgesic, and antipyretic effects. Aximexine acts at various stages of the inflammatory process. Inhibits prostaglandin synthesis and histamine release, and acts as a bradykinin and serotonin antagonist. It also inhibits complement activity and the release of hyaluronidase. Its membrane stability properties can prevent the release of proteolytic enzymes, thereby inhibiting the exudation and proliferation of inflammatory processes. Early animal experiments have shown that it has strong anti-inflammatory, analgesic, and

antipyretic effects. Subsequent clinical and pharmacological studies have found that Aximexin not only has at least equivalent therapeutic effects to Indomethacin, but also has a lower incidence of gastrointestinal adverse reactions and better tolerability when used in the short term. So many internists believe that it is the most effective nonsteroidal anti-inflammatory drug. Aximexine is widely used in clinical practice. This study aims to evaluate the effectiveness and safety of Aximexine in the treatment of axial spondyloarthritis.

II、Research objective

Evaluate the efficacy and safety of Aximexine sustained-release capsules in the treatment of axial spondyloarthritis.

III、Study population

This study plans to include 150 patients with axial spondyloarthritis aged 18-65 years (including the critical value).

IV、Research Design

If you decide to participate in this study, your doctor will first ask you to sign this informed consent form, and then evaluate whether you are suitable to participate in this study before starting treatment.

(1) Before you enter the study, the doctor will evaluate you in the following aspects: asking for your demographic information (such as name, gender, age, ethnicity, education level, etc.), past lifestyle habits (such as smoking history, alcohol consumption history, etc.), medical history and family history, medication and treatment used in previous axSpA treatment, and conducting professional examinations such as height and weight, radiology (sacroiliac joint), vital signs, physical examination, laboratory tests (blood routine, liver and kidney function, urine routine, C-reactive protein, erythrocyte sedimentation rate, etc.), ASDAS score, concomitant medication/treatment, adverse events, etc.

(2) If you meet the eligibility criteria and agree to participate in the study, during the treatment phase, you will begin to receive the Aximexine Extended Release Capsule regimen: you will begin to receive:

Take Aximexine Extended Release Capsules: 1 capsule/time, once daily, for 4 weeks of treatment.

Your supervising physician will adjust the dosage based on your individual condition and tolerance.

The examination items during the treatment period include weight, vital signs, physical examination, laboratory tests (blood routine, liver and kidney function, urine routine, C-reactive protein, erythrocyte sedimentation rate, etc.), medication administered by the research center, efficacy evaluation (VAS score, ASDAS score, BASDAI score, BASFI score, ASAS HI score, BASMI score), concomitant medication/treatment, adverse events, etc. The doctor will inquire about any discomfort you experienced during the study and any other new treatments. Meanwhile, your research doctor will further consider whether you are suitable to continue the trial based on your condition.

(3) When the study is completed or you wish to end the study early, for your safety, an evaluation for ending treatment or early withdrawal needs to be arranged. This evaluation will be completed within 3 days after the last medication, including vital signs, physical examination, laboratory tests (blood routine, liver and kidney function, urine routine, C-reactive protein, erythrocyte sedimentation rate, etc.), efficacy evaluation (VAS score, ASDAS score, BASDAI score, BASFI score, ASAS HI score, BASMI score), concomitant medication/treatment, adverse events, and other examinations. The doctor will also inquire about any discomfort you experienced during the study period and any other new treatments.

All checks conducted during the research process are to determine whether you are suitable to continue participating in this study and to ensure your safety. You need to inform your research doctor or nurse about the medication you are taking and the treatment you are undergoing. The doctor will ask if you feel uncomfortable after taking the medication and if you have followed the doctor's medication advice.

V、Possible adverse reactions, risks, and discomfort

The possible adverse reactions of Aximexine sustained-release capsules include occasional nausea, vomiting, abdominal pain, loss of appetite, occult blood in the stool, gastrointestinal ulcers, headache, dizziness, drowsiness/fatigue, tinnitus, etc.

More detailed information is described in the drug manual. There are risks associated with treatment, as the disease itself, as well as other existing comorbidities or drug combinations, may lead to undiscovered or unpredictable adverse reactions in research.

Before each visit to medication, the researcher will conduct an examination/evaluation of you. Only those who meet the conditions can continue medication, otherwise treatment should be delayed or the study treatment should be terminated.

Researchers will monitor the side effects of drugs in the research protocol. If you experience any side effects or discomfort during the trial, it is crucial to report it immediately to the researchers. Researchers may give you other medications to control side effects. If you or your researchers believe that you cannot tolerate these side effects, the study drug may be reduced, suspended, or even completely discontinued, and you may withdraw from this study.

VI、Possible benefits

By participating in this clinical study, your disease may be alleviated, but it is also possible that the expected effect may not be achieved, and even intolerable drug side effects may occur; Accepting the treatment in this study may not directly benefit you, but your participation will help doctors further research and understand this type of disease, and improve the diagnosis and treatment level of this disease in the future. We would like to express our gratitude for your participation in scientific research and contribution to the development of medicine!

VII、Regarding fees and compensation

The drug used in this study has been launched in China, and the relevant examinations are routine in clinical practice, which will not increase your additional costs. The medical examination and treatment expenses related to the research need to be borne by you.

If you combine the treatment and examination required for other diseases, as well as the cost of switching to other treatments due to ineffective treatment, it will not be within the scope of free treatment. We will observe potential side effects/adverse reactions of drug treatment through regular blood function checks, and take measures to prevent and treat them. If serious adverse reactions related to the investigational drug occur, we will provide treatment related to this serious adverse event.

Although this study was conducted under the premise of ensuring your safety, there may still be unforeseeable serious adverse reactions that could lead to health damage. We have purchased insurance for this clinical study to protect your reasonable rights and interests during the study period.

If the trial subjects participate in drug clinical trials during the insurance period and experience adverse events due to drug adverse reactions, resulting in personal injury or death to the trial subjects who use the trial drug, related drugs, or directly participate in the trial activities, relevant compensation shall be made in accordance with the laws of the People's Republic of China (excluding the laws of Hong Kong, Macao, and Taiwan) and the relevant provisions of clinical trial insurance.

To thank you for participating in this experiment and to compensate you for any transportation, meal, work, and other expenses that may arise from your participation in the study, this research will provide you with reasonable economic subsidies. If you complete all the required visits, you will receive a total subsidy of RMB 500. The subsidy will be paid to you in a timely manner through bank transfer based on the actual number of visits you have completed, after each visit procedure is completed according to regulations.

VIII、Confidentiality of Personal Information

Any personal information and data obtained during the research process will be strictly kept confidential. The information that can identify your identity will not be disclosed to members outside the research team unless your permission is obtained. Any public report regarding the results of this study will not disclose your personal identity. We will make every effort to protect the privacy of your personal medical information within the scope permitted by law.

According to medical research ethics, research data will be available for public access and sharing, except for personal privacy information. Access and sharing will be limited to web-based electronic databases to ensure that no personal privacy information is leaked.

IX、How to obtain more information?

You can raise any questions about this research at any time and receive corresponding answers. If there is any important new information during the research process that may affect your willingness to continue participating in the study, your doctor will notify you promptly.

X、Principle of Participation

Whether to participate in the research depends entirely on your willingness. You may refuse to participate in this study or withdraw from it at any time during the study process, without affecting your relationship with the doctor or any loss of medical or other benefits to you.

For your best interests, doctors or researchers may suspend your participation in this study at any time during the research process.

If you decide not to participate in this study, your doctor will provide you with other appropriate treatment options or methods. The research doctor will discuss with you the risks and benefits of alternative treatments.

XI、What should we do now?

Whether or not to participate in this study is up to you (and your family) to decide.

Before making the decision to participate in the study, please try to ask your doctor as many questions as possible.

Thank you for reading the above materials. If you decide to participate in this study, please inform your doctor and he/she will assist you

Arrange all matters related to research. Please keep this information.

Informed consent form Agree signature page

Agreed statement:

I have read the above introduction about this study and have had the opportunity to discuss and raise questions with doctors regarding this research. All the questions I raised received satisfactory answers.

I am aware of the risks and benefits that may arise from participating in this study. I am aware that participating in the research is voluntary, and I confirm that I have had sufficient time to consider it. I also understand that:

I can consult the doctor for more information at any time.

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 also aware that if I withdraw from the study midway, especially due to medication reasons, informing the doctor of any changes in my condition and completing the corresponding physical and chemical examinations would be very beneficial for the entire study.

If I need to take any other medication due to changes in my condition, I will seek the doctor's advice beforehand or truthfully inform the doctor afterwards.

I agree to allow the ethics committee of the drug regulatory authority or the representative of the sponsor to access my research materials.

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

Finally, I have decided to agree to participate in this study and promise to follow medical advice as much as possible.

Subject name：_____；Subject signature：_____；

Date：_____；Tel.：_____。

Signature of guardian：

Date：_____； Time：_____

Tel.：_____

Notary Witness Signature Date：_____Time：_____

Tel.：_____

Reason for requiring witness signature _____。

Researcher statement: I confirm that I have explained the detailed information of this study to the subjects, especially the risks and benefits that may arise from participating in this

study, and have answered all relevant questions from the subjects. The subjects voluntarily agreed to participate in this study. This informed consent form is in duplicate, with both the researcher and the subject retaining one signed informed consent form.

Research doctor's name：_____Signature of research doctor：_____

Research doctor's phone：_____Date：_____