Informed consent for clinical treatment

Project Name:Clinical efficacy and safety of real-world patients with refractory rheumatoid arthritis (D2TRA) treated with Abatacept Combined With JAK Inhibitor /02

Scheme version number and version date:02/2022-05-03

Version number and date of informed consent:02/2022-05-03

Dear subjects:

We invite you to participate in the efficacy and safety of Abatacept Combined With JAK Inhibitor in the treatment of refractory rheumatoid arthritis approved by Zhejiang Provincial People's hospital. This study will be carried out in Zhejiang Provincial People's Hospital, and 120 subjects are expected to participate voluntarily. This study has been reviewed and approved by the ethics committee of Zhejiang Provincial People's hospital.

These instructions will provide you with some information to help you decide whether to participate in this clinical study. Whether you participate in this study is entirely voluntary, and your decision will not affect your normal diagnosis and treatment rights and treatment in our hospital. If you choose to participate in this study, our research team will try its best to ensure your safety and rights in the research process!

These instructions provide you with some information to help you decide whether to participate in this clinical study. Please read it carefully. If you have any questions, please ask the researcher in charge of the study.

Objective:

Rheumatoid arthritis (RA) is an autoimmune disease dominated by chronic synovitis. It is one of the most common diseases of inflammatory joint damage in connective tissue diseases. The disease mainly invades small joints such as hand, wrist and foot. Its clinical manifestations are symmetry, synovial inflammation and extraarticular lesions. Without active treatment for a long time, joint activity will be significantly limited or even disabled, which will cause huge economic burden to the patient, his family and society. At present, the main drugs for the treatment of rheumatoid arthritis include NSAIDs, DMARDs, glucocorticoids,, biological agents and traditional Chinese Medicine.

NSAIDs are the first generation of therapeutic drugs for RA.Although NSAIDs are widely used, with rapid onset and good analgesic effect, they can not control the progress of the primary disease. Moreover, with the further validation of the experiment, it was found that NSAIDs, especially selective COX-2 inhibitors, would increase the incidence rate of cardiovascular events.

Anti rheumatic drugs for improving the condition,Its common feature is that it can improve the condition and delay the progress of the disease. One of the disadvantages is that the effect is slow, and the other is that they all have different side effects.Gastrointestinal reactions may occur after long-term use, with occasional hair loss, skin redness, pruritus or rash, pseudomembranous or hemorrhagic enteritis. When applied in large doses, it will cause liver and kidney function damage, drug-induced interstitial pneumonia, leucopenia and thrombocytopenia and other symptoms.

Glucocorticoids have strong anti-inflammatory and immunosuppressive effects, so they are used to treat rheumatic diseases. They are the first-line drugs for the treatment of a variety of connective tissues.Taking glucocorticoids for a long time has many adverse reactions, including infection, hypertension, hyperglycemia,

osteoporosis, withdrawal rebound, obesity, peptic ulcer and so on. Therefore, its efficacy and side effects should be weighed in clinical application.

Method:

If you agree to participate in this study, we will number you and establish medical records.In the study, no intervention factors were applied to you. This study is aimed at the observation of refractory RA patients who need to be treated with Abatacept Combined With JAK Inhibitor. Therefore, you need to be able to go to the hospital for outpatient follow-up before drug treatment and at 4, 8, 12, 16, 20 and 24 weeks after treatment, and test the DAS28 score and relevant laboratory indexes (DAS28 score, C-reactive protein, ESR, bone metabolism index, blood routine, liver and kidney function), It is used to record the changes of your condition and observe the clinical efficacy and safety ofAbatacept Combined With JAK Inhibitor .

Possible risks and uncertainties:

All information will be confidential to you. You may have dizziness and other adverse reactions during drug treatment. We will adjust or stop the scheme accordingly to minimize the risk of adverse reactions.

Expected benefits:

Testing your specimen will help to diagnose the disease, provide necessary suggestions for your treatment, or provide useful information for disease research.

Alternative treatmen:

You can choose to participate in this study or you may not be able to improve your health:

1.Do not participate in this study and continue your routine treatment. There are several conventional treatment methods: oral traditional anti rheumatic drugs or non steroidal anti-inflammatory drugs

2.Participate in other studies.

3.Do not receive any treatment.

Please consult with your doctor about your decision

free treatment:

Any expenses incurred by the subjects in participating in the study, including medical expenses, drug expenses and inspection expenses incurred from observation indicators during follow-up, shall be borne by the subjects themselves.

compensate :

There is no insurance in this study. In case of any damage related to the study, the researcher will compensate the subjects' medical fees, treatment fees, examination fees and mental losses in accordance with the laws and regulations.

Confidentiality:

The information about you obtained in any research will be kept in the scientific research department of the Institute in the form of confidential documents, which will be strictly confidential and only used for this research.

Any public report on the results of this study will not disclose your personally identifiable information. We will make every effort to protect the privacy of your personal medical data to the extent permitted by law.

Voluntary:

You can choose not to participate in this study, or notify the researcher to withdraw from the study at any time. Your data will not be included in the research results, and your medical treatment and rights will not be affected. If you need other treatment, or you do not comply with the study plan, or you have research-related injuries, or for any other reason, the study physician may terminate your continued participation in the study.

Subject obligations:

As a research subject, you have the following responsibilities: truthfully provide the truth about your medical history and current physical condition; Inform the study doctor of any discomfort he experienced during the study; Do not take restricted drugs, food, etc.Tell the study doctor whether he has participated in other studies recently or is currently participating in other studies.

contact information:

You can keep abreast of the information and research progress related to this study at any time. In case of any new safety information related to this study, we will notify you in time. If you have any questions related to this study, or you have any discomfort or injury during the study, or you have any questions about the rights and interests of the participants in this study, you can contact Dr. huangyanjing at 13857108462.

If you have any questions or demands about the rights and health of participating in this study, you can contact the ethics committee of Zhejiang Provincial People's Hospital at 0571-85893643.

Informed consent signature page

I have read the above introduction about this study, and the research doctor has explained the research content to me in detail. Before signing the informed consent form, I have no more doubts about the study to consult. On this basis, I voluntarily participate in the clinical study introduced in this article, and my decision is based on a full understanding of the possible risks and benefits of participating in this study. In addition, the researcher did not use deception, inducement, coercion and other means to force me to agree to participate in the study, and I knew that I could unconditionally withdraw from the study at any stage.

This informed consent shall be signed by the guardian or legal representative of the subject due to his incapacity or limited capacity.

Subject signature_____ Signature of legal representative_____

Date _____

Contact information of subjects_____ Contact information of legal representative_____

I have accurately informed the subject of this document. He / she has accurately read this informed consent form and has the opportunity to ask questions.

Investigator signature_____

Date _____

(Note: if the subject is illiterate, the signature of the witness is required; if the subject is incapacitated, the signature of the agent is required)