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informed consent form

Dear Patient:

The doctor has diagnosed that you have immune thrombocytopenia. We invite you to participate in a clinical study entitled "Efficacy and Safety of Hytrombopag Ethanolamine Tablets in the Treatment of Thrombocytopenia in Patients Scheduled for Elective Surgery." The study protocol has been reviewed and approved by the Ethics Committee of Chengdu City Third People's Hospital for clinical study.

Before you decide whether or not to participate in this study, please read the following as carefully as possible. It will help you understand the study and why it is being conducted, the procedures and duration of the study, and the benefits, risks, and discomforts of participating in the study. If you wish, you can also discuss it with your relatives and friends, or ask your doctor for an explanation to help you make a decision.

I. Background and purpose of the study

1.1 Disease burden and treatment status

Perioperative bleeding is a thorny problem in surgical operation, and it is also an important reason for rapid recovery after operation.[1]Platelet is a blood cell directly involved in clot formation and inflammation regulation, its main function is to participate in the body's coagulation and hemostasis. Thrombocytopenia leads to a greatly increased risk of bleeding and transfusion. Thrombocytopenia is very common in perioperative period,Li [2]A retrospective study conducted by et al showed that cirrhosis patients with severe thrombocytopenia (PLT≤50×10 μ g/L) had a higher incidence of major bleeding events after invasive procedures (4.9% VS 1.6%, P = 0.008). Perioperative thrombocytopenia may increase bleeding risk, prolong hospital stay, lead to organ damage, increase medical costs, and in severe cases, lead to death.

The optimal drug regimen for increasing platelet count in perioperative pat ients preparing for invasive procedures should consider the underlying disease. Glucocorticoids or immunoglobulin should be given first in immune thrombocyt openia. There are few drug related studies on perioperative platelet count incre ase, and there is more evidence for thrombopoietin receptor agonists (TPO-RA). Avaratrombopag is also the only platelet boosting drug approved by the Natio nal Medical Products Administration (NMPA) for patients with thrombocytopeni a associated with chronic liver disease undergoing elective diagnostic procedure s or surgery. Immunoglobin can be used when rapid platelet boosting is require d, especially in patients before pregnancy or delivery, such as emergency surge ry.

Thrombopoietin receptor agonist (TPO-RA) activates tyrosine kinase/signal transducer and activator of transcription (JAK/STAT) by acting on the transmembrane domain of human TPO receptor, induces megakaryocyte survival, proliferation and differentiation, stimulates platelet production, and is not resistant to drug resistance.

As a novel oral thrombopoietin receptor agonist, hytrombopag obtained

synergistic and attenuated therapeutic effects through structural optimization, especially in safety, and its effect on bilirubin metabolism was superior to eltrombopag. In a clinical trial to explore the efficacy and safety of hytrombopag in ITP patients, the results showed that hytrombopag was reliable in efficacy, rapid plate rise, improved platelet response rate, and good safety and tolerability.

Based on the above results, we intend to conduct a study on the efficacy and safety of hytrombopag in the treatment of patients with preoperative thrombocytopenia.

1.2 Purpose of this study

To study the efficacy and safety of hytrombopag ethanolamine tablets in the treatment of thrombocytopenia in patients scheduled for elective surgery.

1.3 Study Participants and Expected Number of Participants

Participating units Chengdu City Third People's Hospital, is expected to include 55 participants.

2. Who should not participate in the study

1. History of allergy to TPO-RA drugs;
2. Severe bleeding symptoms, such as upper gastrointestinal bleeding, bleeding of important organs, intracranial hemorrhage, etc.;
3. thrombotic diseases such as pulmonary embolism, arterial thrombosis and disseminated intravascular coagulation (DIC);
4. Anti-human immunodeficiency virus antibody or anti-Treponema pallidum specific antibody positive;
5. Congestive heart failure New York Heart Association (NYHA) class 3 or 4;
6. History of angina pectoris, myocardial infarction or cerebral infarction within 6 months prior to screening;
7. Active infections that are difficult to control;
8. Pregnant or lactating women;
9. researchOther conditions judged unsuitable for inclusion in the study by the investigator.

III. What will be required if I participate in the study?

1. Before you are enrolled in the study, your doctor will ask you about your medical history and assess your condition. If you meet the inclusion criteria and you volunteer to participate in the study, you will sign an informed consent form. If you do not want to participate in the study, it will not prejudice you or affect your medical care.

2. If you volunteer to participate in the study, the following steps will be followed:

Before the start of the trial, we will check the baseline blood routine and liver function of the subjects.Received treatment with Hytrombopag Ethanolamine Tablets, specific dosing regimen: 7.5 mg, once daily, oral on an empty stomach before bedtime, lasting up to 14 days,PLT$\geq 100\times10^9$/L. Monitor the hemogram until PLT$<100\times10^9$/L. During the treatment period, blood routine was monitored once every 7

days,PLT≤30×10^9/L or ≥300×10^9Blood routine will be monitored every 3 days at/L. Subjects will have an end-of-treatment visit within 7 days after treatment discontinuation, followed by a 30-day safety follow-up period。

If you also have other underlying diseases that require further examination and treatment, there will be no interference in this study.

3. Other matters requiring your cooperation

During the course of the study, new information about the study methods may appear. If new information becomes available, your study doctor will inform you and discuss with you whether you still want to participate in the study. If you decide to continue in the study, you may be asked to sign a new informed consent form. During the follow-up phase, the doctor may learn about you by telephone, outpatient follow-up, etc.

IV. POSSIBLE BENEFITS OF PARTICIPATION IN THE STUDY

If you participate in this study,It is expected to quickly increase platelet count, meet surgical requirements, and reduce bleeding risk.。But there are no guarantees.

V. Possible adverse reactions, risks, discomfort and inconvenience of participating in the study

If you experience any discomfort or new changes in your condition during the study, or any unexpected circumstances, whether related to the study or not, you should inform your doctor promptly, and he/she will make a judgment and give appropriate medical treatment.

VI. RELATED COSTS

The fees for blood routine test, liver function test and other laboratory tests participating in this study shall be paid by themselves according to the outpatient or inpatient charging process of the hospital;Hytrombopag Ethanolamine Tablets is currently reimbursed only for relapsed and refractory chronic primary immune thrombocytopenia and severe aplastic anemia. If you do not qualify for Medicare reimbursement and choose to participate in this study, you will receive half of the medication for free during treatment.(For example, if you need 2 boxes of Hytrombopag for treatment, you will only need to pay for 1 box and buy it by box). If you also need treatment and examination for other diseases, as well as the cost of switching to other treatments due to ineffective treatment, you will have to bear the cost yourself.However, the cost of subsequent data collection and analysis is borne by the hospital.

During the study, doctors will do their best to prevent and treat injuries that may occur as a result of this study.

VII. Confidentiality of Personal Information

Your medical records will be kept at the hospital and will be accessible to investigators, study authorities and ethics committees.Any public report on the results of this research will not disclose your personal identity. We will make

every effort to protect the privacy of your personal medical data to the extent permitted by law.

In accordance with medical research ethics, research data will be available for public inquiry and sharing, except for personal privacy information, which will be limited to web-based electronic databases to ensure that no personal privacy information will be leaked.

8 How can I get more information?

You can ask any questions about this study at any time and get answers accordingly. If there is any important new information during the study that may affect your willingness to continue in the study, your doctor will inform you in a timely manner.

IX. Voluntary opt-in and drop-out

You can refuse to participate in the study or withdraw from the study at any time during the study without affecting your relationship with the doctor or any loss of medical or other benefits to you.

Your doctor or investigator may discontinue your participation in the study at any time during the study in your best interest.

If you do not participate in the study or withdraw from the study halfway, you can also choose to receive platelet transfusion to achieve the platelet count required for surgery, or take other methods such as glucocorticoids, intravenous immunoglobulin, recombinant human thrombopoietin and thrombopoietin receptor agonist eltrombopag, anti-CD20 monoclonal antibody, etc. The doctor will inform you of the risks and costs of relevant treatment methods after comprehensive evaluation.

X. What to do now?

It is up to you (and your family) whether to participate in this study.

Ask your doctor as many questions as possible before you decide to participate in the study.

Thank you for reading the above materials. If you decide to participate in this study, please tell your doctor and he/she will arrange everything for you about the study. Please keep this information.

declaration of consent

I have read the above introduction to this study and have had the opportunity to discuss and ask questions about this study with my doctor. All my questions have been answered satisfactorily.

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

- I can always ask my doctor for more information.

● 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, especially for medical reasons, it would be beneficial for the study if I told my doctor about my condition and completed the physical and chemical examinations.

If I need to take any other medication because of my condition, I will ask my doctor beforehand or tell my doctor afterwards.

I agree that the Ethics Committee of the Drug Administration or the sponsor's representative can access my study data.

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

In the end, I agreed to participate in the study and promised to do my best to comply.

Patient Signature:_____
DD/MM/YY
Tel:_____

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

Signature of physician:_____
DD/MM/YY
_____