Project Name: BTD program and BCD program for the treatment of light amyloidosis: prospective, randomized, controlled clinical study program No.: v1.4 version date: August 9, 2019
study unit: Guangdong People's Hospital
sponsor: Guangdong People's Hospital
thank you for your attention to this clinical study project! This informed consent is to introduce you to the project "prospective, randomized and controlled clinical study of BTD regimen and BCD regimen in the treatment of light amyloidosis". You have the right to choose whether to participate in this study or not. Information about this study is provided below to help you make your choice. Please read the following carefully. If you have any questions, please ask the researcher to make sure you understand the content correctly. If you decide to participate in this study, please sign on the last page.

Objective
There is no standard treatment plan for light chain (AL) amyloidosis at present. The purpose of this study is to explore the difference between bortezomib + thalidomide + dexamethasone (VTD) plan and bortezomib + cyclophosphamide + dexamethasone (VCD) plan, and to provide more clinical evidence for the standard treatment of AL amyloidosis.

Research contents
Bortezomib (gjz-h20120299) is a proteasome inhibitor, thalidomide (gjz-h32026129) and cyclophosphamide (gjz-h20110407) are immunosuppressants, which play a certain role in the treatment of AL amyloidosis and plasma cell disease.
VTD group: bortezomib (1, 8, 15, 22 days, 1.3mg / m2, subcutaneous injection); thalidomide (long-term oral, 100mg, oral); dexamethasone (1, 2, 8, 9, 15, 16, 22, 23 days, 40mg, oral) as a course of treatment, the patients will complete six courses of treatment, the overall observation time is one year after the end of treatment. VCD Scheme Group: bortezomib (1, 8, 15, 22 days, 1.3mg / m2, subcutaneous injection);

cyclophosphamide (1, 2 days, 900MG / m2, intravenous drip); dexamethasone (1, 2, 8, 9, 15, 16, 22, 23 days, 40mg, oral administration) as a course of treatment, the patients will complete 6 courses of treatment after entering the group, the overall observation time is treatment 1 year after the end.

Before treatment and every month in the treatment cycle, relevant examinations should be done [blood routine (1 EDTA tube, 2ml peripheral blood), liver and kidney function (1 separate rubber tube, 5ml peripheral blood), infection index (2 glass drying tubes, 2ml peripheral blood), 24-hour urine protein quantification, blood light chain (1 glass drying tube, 2ml peripheral blood), urine light chain (1 urine tube, 2ml urine)], regular Bone marrow examination to evaluate the efficacy [bone marrow smear (1 EDTA tube, 0.5ml of bone marrow fluid, once every three months), bone marrow flow cytometry (1 EDTA tube, 3ml of bone marrow fluid, once every three months), bone marrow fusion gene fish examination (2 EDTA tubes, 4ml of bone marrow fluid, once at the initial diagnosis), bone marrow biopsy, etc.]. According to the research process and clinical visit plan, the chest CT, color Doppler echocardiography, ECG, 24-hour ambulatory blood pressure and other examinations were completed during the treatment. These tests are also necessary for your follow-up and examination in the treatment of AL amyloidosis.

Risk of participation in this study

In the study, the drugs that the patients will use have the following side effects: (1) bortezomib may have the following side effects in the use process: 1. Blood system: anemia, thrombocytopenia; 2. Gastrointestinal tract: constipation, diarrhea, nausea, vomiting, anorexia; 3. Infection; 4. Benign, nausea and undefined tumors; 5. Systemic reaction: fatigue, lethargy, etc. （2） During the use of cyclophosphamide, the following side effects may occur: 1. 2. Liver damage. 3. Myelosuppression. 4. Immunosuppression, easy to infect. 5. Gastrointestinal tract: anorexia, nausea, vomiting, stomatitis, etc. 6.

Hair loss, rash, mucosal ulcer, etc. 7. Renal hemorrhage, bladder fibrosis, hemorrhagic cystitis, hydronephrosis, vesicourethral reflux, etc. 8. Carcinogenesis. 9. Pulmonary fibrosis. 10. Blurred vision, etc. * (three) during the use of hormone drugs, the following side effects may occur: 1. gastrointestinal irritation, abdominal pain, nausea, vomiting, peptic ulcer, even gastrointestinal bleeding, perforation; 2. immunosuppression, easy to infect; 3. osteoporosis, including pathological fractures, vertebral compression fractures, femoral head necrosis, 4. diabetes, 5. water sodium retention, edema, hypertension, 6. full moon face. , centripetal obesity, purple lines, acne; 7. Menstrual disorders; 8. Children's growth and development are inhibited; 9. Mental disorders. （4） The main side effects of thalidomide are: 1. Teratogenicity. 2. Dry oral mucosa. 3. Burnout. 4. Rash. 5. Constipation, nausea and abdominal pain. 6. Neuralgia, postherpetic neuralgia, peripheral neuropathy, sensory abnormality, sensory disturbance, dizziness (excluding vertigo), headache, taste disturbance, 7. Hyperbilirubinemia, hepatitis, alt, AST, ALP and γ - glutamyltransferase. 8. Allergic reaction. 9. Thrombocytopenia, anemia, neutropenia, lymphocytopenia, pancytopenia, febrile neutropenia, septicemia, bacteremia, leukopenia. Disseminated intravascular coagulation is rare. Platelet dysfunction may also occur. 10. Blurred vision, conjunctival infection and irritation. Herpes oculi is rare. Hearing loss. Bilateral deafness is rare. According to the literature reports, the main side effects that may be caused by the combination of drugs include infection (7-10%), anemia (4.1-9.5%), gastrointestinal symptoms (3.5-5.3%), peripheral neurotoxicity (12-21%). Doctors will regularly detect the side effects of drugs and give preventive and treatment measures to reduce the damage of side effects of drugs. These adverse events are not necessarily related to drugs. If the symptoms are mild, special treatment is not needed. If there are adverse events related to the study, the study doctor will take appropriate treatment measures according to the situation.

Benefits of participating in this study

During your participation in this study, you will receive comprehensive medical services and standardized treatment of amyloidosis. During the treatment, we will inform you the results of each examination, evaluate the safety of the drug and deal with possible adverse events.

Voluntary participation / withdrawal from the study

This study is approved by the ethics committee of our hospital. The subjects are totally voluntary. You can refuse to participate or withdraw at any time. You will not be punished or lose your rights and interests, and will not be treated unfairly. If you want to withdraw from the study, you must inform the research doctor. If you need other treatment, or do not follow the study plan, or have injury related to the study or for any other reason, you can be withdrawn from the study without your consent. If the study doctor is sure that it will be bad for you to continue to participate in the study, he can terminate your continued participation in the study at any time, or even without your consent, if You quit the study in advance, and your doctor will ask you to go to the hospital for the final examination and evaluation (including physical examination and laboratory examination). If you quit the study, to the extent permitted by the relevant laws / regulations, the research materials obtained before you quit may still be adopted.

Cost description of participating in the study

The implementation of the study plan needs to be carried out by patients in hospital. Therefore, the cost of drug use and inspection is the inpatient cost, which is borne by the patients themselves. No free drugs and inspection.

Subjects cooperation

During the whole study period, the subjects will be treated in the form of hospitalization according to the arrangement of the researchers, and your blood, urine and bone marrow samples collected during the study period will be tested. The researchers will determine the treatment time of the next treatment course according to the patient's condition changes during each treatment course.

Protection of privacy

The data of this study will be finally archived in Guangdong People's Hospital, and the research results may also be published. But your identity will not be revealed in the publication.

Contact information

For research related injuries or discomfort during the research, please contact Dr. Li Sheng, researcher, at 13824454728. If you have any questions about the rights and interests or ethics of subjects in this study, please contact the ethics committee of Guangdong People's Hospital at 83827812-20984

After signing the informed consent form, I agree: (the following "I" refers to the subject) A kind of I have read this informed consent.

A kind of I have the opportunity to ask questions and all questions have been answered.

A kind of I understand that participation in this study is entirely voluntary.

A kind of As described in this consent, I agree to allow the sponsor, clinician and interested parties to use and share my medical information to the extent permitted by law.

A kind of I can choose not to participate in this study, or withdraw after informing the study doctor at any time. I will not be punished or lose any due benefits.

A kind of If I need other treatment, or if I fail to follow the study plan, or if there is a study-related injury or for any other reason, the clinician can withdraw me from the study without my consent.

A kind of If for any reason I withdraw from this study, the researchers may request some final examination for me.

I will receive a signed copy of the informed consent.

Subject's signature: Date: MM DD YY;

Witness's signature: Date: MM DD YY;

Researcher's signature: Date: MM DD YY;

Researcher's phone number: