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NCT：Not yet allocated

General Investigational Plan

Evaluate the efficacy and safety of the natural plant medicine compound BBD-1 multi-target immune enhancement targeting agent in the treatment of hypersensitivity reaction (IgA) vasculitis.

Comparing the efficacy of natural plant medicine compound BBD-1 multi-target immune enhancement targeting agent with glucocorticoids, providing reference for clinical doctors to register BBD-1 multi-target immune enhancement targeting agent and use it reasonably and standardly in the future

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1. IgA vasculitis is a common vascular allergic disease, and its etiology is not yet clear. It may involve factors such as infection, immune disorders, and genetics. It belongs to the category of immune diseases. This disease can be divided into simple type, abdominal type, joint type, renal type, and mixed type allergic purpura according to the location of onset. The annual incidence rate is about 6.1 to 55.9 cases per 100000 people. The highest incidence rate is among children aged 2 to 6 years. When the kidneys are affected, this condition is called IgAV nephritis (IgAVN), affecting approximately 20% to 80% of IgAV patients, making it one of the most common secondary glomerular diseases in this population. Meanwhile, the skin redness, itching, and joint pain caused by IgA vasculitis also seriously affect the quality of life of patients. Most IgAVN cases are mild or self limiting; However, some patients may experience severe kidney involvement, manifested as nephrotic syndrome, significant proteinuria, elevated serum creatinine levels, hypertension, persistent proteinuria, and kidney biopsy results showing more than 50% crescent shaped involvement. Research has shown that approximately 10% to 20% of patients with moderate to severe proteinuria caused by IgAVN may develop end-stage renal disease (ESRD), and persistent proteinuria has been identified as an independent risk factor for poor prognosis of IgAVN. At present, clinical treatment mainly relies on immunosuppressants such as nonsteroidal anti-inflammatory drugs, glucocorticoids, anti allergic and antihistamines, anticoagulants, corticosteroids, calcineurin inhibitors (CNI), mycophenolate mofetil (MMF), cyclophosphamide (CTX), etc. However, some patients may not respond well to conventional treatment, and long-term use of these drugs may lead to various adverse reactions, including infections, metabolic disorders, and growth disorders.

2. Previous studies have confirmed that BBD-1 multi-target immune enhancement targeting agent is effective and safe in treating hypersensitivity reaction (IgA) vasculitis. After 1 hour of intervention and treatment with BBD-1 multi-target immune enhancing targeted agent, itching disappeared and pain significantly reduced. After 24 hours, the purpura decreased, and after 48 hours, the purpura significantly decreased. After 72 hours, the purpura and pain basically disappeared, and reached the clinical cure standard after 96 hours.

3. Number of participants: 300 in Phase III clinical trials.

4. Inclusion criteria: Medically confirmed small vessel vasculitis with IgA deposition IgA vasculitis; Purpura and/or involvement of at least one organ in the kidneys, joints, or intestines.

5.Drug comparison: Glucocorticoids

Participant Group	Intervention/Treatment
Natural herbal compound BBD-1 multi-target immune enhancing targeting agent Lasting for 14 days	Natural herbal compound BBD-1 multi-target immune enhancing targeting agent • 8 capsules three times a day (morning, middle and evening) each time, 24 capsules per day (capsule) and 10 sprays on the affected area (spray) (the dosage of children above is halved)
Placebo control group placebo Placebo, lasting for 14 days	Drug glucocorticoid prednisone: 0.5-1 mg/kg per day for children and 30-40mg/d for adults, taken in divided doses, gradually reduced after symptom relief (such as 10% reduction per week).