Study on the effect of vestibular rehabilitation treatment (VRT) on patients with unsteadiness after intratympanic gentamicin in Menière's disease

Informed Consent Form

Dear Sir/Madam,

We will invite you to participate in a clinical study. The title is "Study on the effect of vestibular rehabilitation treatment (VRT) on patients with unsteadiness after intratympanic gentamicin in Menière's disease". Before you participate in this study, please carefully read this informed consent form and make a careful decision on whether to participate in this study. You can ask your research doctor/researcher anything you don't understand and have them explain it to you until you fully understand. Before making the decision to participate in this study, you can have thorough discussions with your family and friends. If you are participating in another study, please inform your research doctor or researcher. The main contents of this study are as follows:

1 Research background:

1.1 Menière's disease is an idiopathic inner ear disease with endolymphatic hydrops, characterized by recurrent dizziness, fluctuating sensorineural hearing loss, tinnitus, and/or aural fullness. For patients with Menière's disease who have poor responses to non-invasive treatments, most can be controlled or alleviated dizziness symptoms through intratympanic gentamicin treatment. Due to insufficient compensation after vestibular dysfunction, some patients may experience residual vestibular symptoms and functional impairments such as unsteadiness after this treatment. Although unsteadiness is not a common vestibular symptom, it still harms the patient's ability to perform daily activities, quality of life, and cognitive and emotional states. At present, vestibular rehabilitation has been proven to be an effective method for controlling vestibular symptoms, and it is speculated that vestibular rehabilitation treatment may also be effective for patients with Menière's disease who experience unsteadiness after intratympanic gentamicin treatment. It is worth exploring whether vestibular rehabilitation treatment can alleviate chronic unsteadiness after intratympanic gentamicin treatment, which may provide new ideas and evidence for the treatment and rehabilitation of patients with Menière's disease, with the aim of improving their daily activity abilities and quality of life.

1.2 This study has been approved by the Ethics Committee of the Eye and Ear Nose Throat (ENT) Hospital of Fudan University, and will comply with international principles such as the Helsinki Declaration to protect the rights and interests of subjects, as well as relevant laws and regulations of China, in accordance with medical ethics and morality.

2 Research design and research process:

2.1 48 patients who visit the Eye and Ear Nose Throat (ENT) Hospital of Fudan University from January 2025 to December 2025 will be selected and divided into two groups: The usual care group (control group) and the vestibular rehabilitation treatment group (experimental group).

2.2 You will be randomly assigned to either the usual care group or the vestibular rehabilitation treatment group.

2.2.1 The usual care group will receive the following treatment interventions:

(1) Drug therapy: Patients will receive pharmacological treatment, including anti-dizziness

medications, diuretics, or hormone therapy, contingent upon the patients' specific clinical presentation.

(2) Health education: Comprehensive health education will be provided to patients, including instruction on medical knowledge related to the disease and vestibular function, prevention of vertigo attacks and falls, and lifestyle adjustments.

2.2.2 The vestibular rehabilitation treatment group will receive the following treatment interventions:

Vestibular rehabilitation plan: This will encompass office-based sessions of vestibular rehabilitation treatment once weekly, supplemented by home-based exercises conducted two or three times daily for the remaining duration of the study. Each home-based exercise session is anticipated to last approximately 20 minutes, with the regimen spanning over a course of 6 months. Patients will need to undergo comprehensive exercise recording during the treatment period and report any adverse events that occur during the treatment.

2.3 When signing the consent form, baseline assessment and collection of demographic and clinical data will be conducted, including age, gender, education, employment, marital status, coexisting systemic diseases, date of onset, duration of symptoms, and affected ear. Participants are required to conduct vestibular functional assessments (FGA, SOT), undergo vestibular laboratory tests (vHIT, caloric test, VEMP), fill out subjective vestibular function questionnaires (MDOQ, VVAS, and VAP), and monitor safety outcomes at the clinic at baseline, 8 weeks after allocation, and 6 months after allocation.

2.4 Confidentiality measures for personal privacy: Your medical records will be kept in the hospital and are only available for researchers to access. When necessary, members of government regulatory agencies or ethics committees may access your personal information in accordance with regulations. The research results will be published in the form of statistically analyzed data, without any identifiable subject information.

3 Inclusion criteria and exclusion criteria:

3.1Inclusion criteria:

Adults aged between 18 and 60 years old;

(2) Conformed to unilateral Menière's disease;

(3) Complained of persistent unsteadiness 1 month after intratympanic gentamicin treatment;

(4) Be willing to sign the informed consent of the study.

3.2Exclusion criteria:

(1) Conformed to neuromuscular disease;

(2) Conformed to severe cervical spine disease;

(3) Conformed to other inner ear disease ;

(4) Conformed to bilateral Menière's disease;

(5) Conformed to comorbidities or potential comorbidities (e.g. overlapping Menière's disease and vestibular migraine);

(6) Concurrent manifestation of psychiatric or psychological disorders;

(7) Previously received intratympanic steroids treatment or other surgical treatments that affect vestibular function.

4 Possible risks and benefits:

4.1 Possible risk: Participants in randomized treatment may not receive the ultimately proven more effective treatment. This study is an intervention study, and adverse reactions may occur during the treatment process. If the following symptoms occur during vestibular rehabilitation treatment, we will stop or modify the vestibular rehabilitation plan, including vomiting, nausea or muscle soreness; a sharp or prolonged pain sensation in the neck, arms or legs; a sensation of ear fullness, hearing loss or tinnitus; double vision or fainting, etc. In fact, vestibular rehabilitation treatment rarely leads to adverse events. If patients encounter any questions during the research process, they can consult with the research doctor.

4.2 Possible benefits: You will not be charged any fees for participating in this study, and the treatment options involved in the study may alleviate your clinical symptoms and enhance your quality of life. During the research period, clinical consultant appointments, weekly phone calls, additional auxiliary examination fees, and reimbursement of commuting expenses will be provided. The clinical research you participate in will help to make a clear diagnosis or effective treatment of Menière's disease in the future, and improve the cure rate of Menière's disease. We would like to express our gratitude for your participation in scientific research and contributions to the development of medicine!

5 Voluntary participation: Your participation in the research is completely voluntary. You can withdraw from the study at any time without any reason. It will never affect your relationship with medical staff and your future diagnosis and treatment.

6 Research fees: Participating in this study will not incur any additional costs for you, and all research fees will be borne by the researcher themselves.

7 Contact person and contact information: If you have any questions about this study, you can directly contact Dr./Researcher Tong Qiling from the Eye and Ear Nose Throat (ENT) Hospital of Fudan University. Contact phone number: 13816520179.

8 This informed consent form is in duplicate, properly kept by both parties, and is valid after being signed by both parties.

Informed consent letter section

I have read the above information and understand the purpose of the study as well as the potential benefits of participating in the study. I have received satisfactory answers to all questions regarding the research procedure and content. I voluntarily sign this informed consent form and voluntarily participate in this study.

Participant Signature:

Signature Date:

Participant contact phone number:

We have read and explained this informed consent form to the research subjects and answered all their questions.

He/she has also understood and agreed to participate in this scientific research.

Signature of researcher:

Date of signature: