Informed consent form

The clinical study of bone-patellar tendon-bone and quasi-anatomical meniscus allograft transplantation technique

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Dear Subjects

We invite you to participate in the research project "Bone-Patellar Tendendon-Bone and Anatomical Meniscus Human Allogeneic Transplantation Technology" approved by Beijing Tsinghua Chang Gung Hospital (project source). An estimated 200 participants will volunteer. This study has been reviewed and approved by the Ethics Committee of Beijing Tsinghua Changgung Hospital.

1. Why was this study being conducted?

Knee ligament injury and meniscus injury are common sports injuries in clinical practice, and although traditional treatment methods can alleviate some symptoms, there are certain limitations in restoring knee joint function and protecting cartilage. In recent years, allogeneic transplantation techniques have shown significant advantages in ligament and meniscus reconstruction, providing patients with new treatment options. The technology is self-administered in the hospital, and the bone-patellar tendon-bone and meniscus used are commercial products, and have obtained Class III registration certificates, ensuring the quality, efficacy and safety of the treatment. The application of osteo-patellar tendon-bone and anatomical meniscus allogeneic transplantation technology aims to solve the shortcomings of traditional treatment methods, restore the function of the knee joint, reduce postoperative complications, and delay the process of knee degeneration through advanced transplantation technology.

2. How many people will participate in this study?

≥ 200 people were divided into transplant group and control group in this institution, and it is currently planned to be a single-center study (at this stage).

3. Inclusion criteria for the subject population of this study

Bone-patellar tendon-bone allograft reconstruction of anterior/posterior cruciate ligament

(1). Anterior/posterior cruciate ligament injuries: These include complete rupture or severe injuries that affect the stability and functional recovery of the knee joint.

(2). Recurrent knee instability: a sensation of displacement associated with joint flexion, particularly in patients who interfere with daily activities or sports.

(3). Knee dysfunction: including unsteady gait and inability to bend or extend the knee, which can seriously affect exercise ability.

(4). Younger, high-activity patients: want to regain exercise and reduce the risk of long-term knee degeneration.

Minimally invasive anatomical human allogeneic meniscus transplantation

(1). Extensive or complete meniscus extraction: resulting in long-term pain, instability, and degeneration of the knee.

(2). Articular cartilage lesions: patients with early-stage degenerative arthritis may be treated with meniscus transplantation to slow progression.

(3). Knee biomechanical abnormalities: patients who wish to return to normal knee load distribution after surgery.

(4). Young or middle-aged patients: high level of joint mobility and long-term recovery of function.

(5). Conservative treatment and failure of traditional surgery: patients whose symptoms persist and cannot be improved.

3. Exclusion criteria for the population of participants in this study

(1) Knee joint has severe osteoarthritis.

(2) There is a risk of active infection or severe immune rejection.

(3) The patient has irreparable ligament damage or deformity correction needs.

4. The research process of this study

（1）. Study objectives: To determine the indications and key clinical needs of bone-patellar tendon-bone allogeneic transplantation and anatomical allogeneic meniscus transplantation. Focus on functional reconstruction and inflammation control in patients with knee ligament and meniscal injury.

（2） Preoperative preparation: This technique is a self-administered technique in the hospital, using bone-Patellar tendon-Bone and meniscus are commercial products that have obtained Class III registration certificates; PassMRI and CT images obtain detailed data on the patient's knee joint structure for precise positioning and design during surgery.

（3）. Surgical implementation plan: 1) Bone-patellar tendon-bone grafting: Precise drilling and ligament channel preparation with arthroscopic assistance to ensure the anatomical fixed position of the graft. Absorbable screws or interface fixation devices are used to ensure

the tension and stability of the implanted ligaments. 2) Anatomical meniscus transplantation: Minimally invasive arthroscopic techniques are used to select a matching meniscus graft according to the size of the patient's knee joint. The high-precision suture technique immobilizes the graft and ensures its fusion with the surrounding soft tissues.

（4）. Postoperative rehabilitation plan: Develop a phased rehabilitation plan, including early activity restriction, intermediate joint function recovery, and later exercise capacity reconstruction. Biomechanical testing and imaging follow-up were used to assess the stability and functional recovery of the graft.

（5）. Efficacy evaluation and data collection: data on postoperative pain scores, range of motion, graft stability and complications were collected. Lysholm score, Tegner score and MRI images were used to analyze the transplantation effect.

（6） Long-term follow-up and technical optimization: Establish a long-term patient database to track and analyze graft survival, arthritis progression, and functional recovery. Based on clinical data, the graft processing, intraoperative technology and rehabilitation program were optimized, and the promotion and application price of technology was improved

5. How long will the study last?

The study will last for 2 years, and we will conduct multiple follow-up visits and collect follow-up information. You can opt out of the study at any time without forfeiting any benefits you would otherwise receive. However, if you decide to withdraw from the study during the study, it is possible that a check-up will be performed after withdrawal due to your safety concerns.

6. Benefits of participating in this study

In this program, you can consult with our doctors at any time to get feedback on your rehabilitation. Able to move towards the goal of returning to sport under the guidance of a person and at a safe, conservative pace.

7. Risks and precautions for participating in this study

There are risks associated with any surgery and anesthesia, and any medication used can have side effects, ranging from mild nausea and rashes to severe anaphylactic shock and even life-threatening. When performing a transplant, a thorough assessment of the potential risks and an emergency plan should be developed to ensure the safety of the procedure and reduce postoperative complications. The following are the main foreseen risks and their corresponding

emergency measures:

（1）. Risk of intraoperative infection

Risk assessment: Despite the minimally invasive technique of surgery, arthroscopic procedures and instrument introduction may still cause infection.

Precautionary measures:

The operating room strictly follows aseptic operation practices, including skin disinfection in the surgical area before surgery, aseptic drapes and autoclaving of surgical instruments. Broad-spectrum antibiotics (e.g., cephalosporins) are used preoperatively and adjusted postoperatively based on infection risk assessment.

（2）. Graft rejection

Risk assessment: allogeneic meniscus and bone-patellar tendon-bone may trigger immune rejection, particularly if histocompatibility is insufficient.

Precautionary measures:

HLA matching and immunological evaluation of donors and recipients were performed before surgery, and donors with high compatibility were selected. The use of cryopreserved allogeneic meniscus reduces immunogenicity.

（3）. Postoperative hematoma formation

Risk assessment: Intraoperative microvascular injury and inappropriate postoperative movement may lead to hematoma in or around the articular tissue.

Precautionary measures:

Attention should be paid to hemostasis during surgery, and electrocoagulation or local compression techniques can be used. Avoid premature weight-bearing and strenuous exercise after surgery, and recommend bed rest and elevation of the affected limb.

（4）. Dislocation or loosening of the graft

Risk assessment: Poor weight-bearing and movement in the early postoperative period can lead to meniscal graft dislocation or loosening.

Precautionary measures: Ensure stable fixation of the graft during surgery, using techniques such as absorbable sutures and suture anchors. Restrict weight-bearing activities

of the knee for 6 weeks postoperatively and encourage the use of knee braces for immobilization. MRI is used to check the stability of the graft at postoperative follow-up, and a second surgical reduction can be considered if loosening or dislocation is found.

（5）. Postoperative joint dysfunction

Risk assessment: patients may present with limited mobility and joint stiffness due to postoperative scar tissue formation and joint adhesions.

Preventive measures: Rehabilitation physiotherapy such as passive range of motion training and muscle strength training should be carried out early postoperatively. Anti-inflammatory drugs are used to reduce the formation of tissue adhesions. Arthroscopic release may be considered in patients with severe adhesions. Personalized rehabilitation training is carried out under the guidance of rehabilitation doctors, and the amount of activity is gradually increased.

（6）. Postoperative pain management

Risk assessment: Postoperative pain is a common problem and may affect the course of recovery.

Preventive measures: intraoperative use of local anesthesia and early postoperative use of analgesic drugs (eg, NSAIDs). Ice and physiotherapy are recommended to help relieve pain after surgery.

8. What are the other medical options available?

Artificial ligament transplantation

9. Confidentiality

Your medical records will be kept intact at Tsinghua Chang Gung Hospital, and we will ensure the confidentiality of your written information, samples and test results. Without your permission, no organization or individual can obtain this information. Your identity will not be disclosed when you publish the research information and data obtained from this project at a scientific conference or in a scientific journal. However, your records may be reviewed to ensure compliance with applicable laws and regulations. The reviewers included relevant national administrative departments, the Ethics Committee of Beijing Tsinghua Chang Gung Hospital, and the project personnel team of Beijing Tsinghua Chang Gung Orthopaedic Sports Center, which was directly involved in the collection of materials.

10. Fees

The study does not increase your additional costs or health insurance expenses. You will not have to pay for the implant, CT scan and everything you need to follow up during the study. Before you agree to participate in this study, you should contact your medical biller/insurance company to find out if your plan will cover the costs of your portion of the study. You can check with your study doctor or researcher for more information about the cost.

11. What compensation can I get?

In order to participate in the expenses of this institute, enjoy the green channel, free of registration fee, and the relevant inspection fees are provided by Yu Jiakuo's research group. Please note: Compensation must be prorated so that the subject will be compensated for the appropriate portion when he or she withdraws from the study. The method of providing compensation is the way in which the subject is compensated.

12. In the event of a study-related injury

If you have adverse reactions or other injuries due to the test, Beijing Tsinghua Chang Gung Hospital will immediately provide necessary medical care, and bear the cost of treatment and corresponding financial compensation in accordance with the relevant laws and regulations.

13. Refusal to participate or withdraw

Before you undergo the trial, you need to ensure that your participation is completely voluntary, that you can choose to decline or withdraw from the trial at any stage, that you will not be discriminated against or retaliated against, and that your medical treatment and rights will not be affected. If you experience serious adverse reactions, or if your study doctor feels that it is not in your best interest to continue participating in the study, he/she will decide to withdraw you from the study. If this happens, we will keep you informed and your study doctor will discuss with you the other options you have. If your doctor thinks that stopping the test abruptly will affect your health, he or she may ask you to come to the hospital for a check-up before stopping the test.

Subject Declaration: I have read the above presentation about this study and am fully aware of the possible risks and benefits of participating in this study. I volunteered to participate in this study.

I agree to □ or refuse □ other studies other than this study utilize my medical records and pathological examination specimens.

Subject Signature: Date: _year_month__day

Subject's contact number: Mobile phone number:

Investigator's Statement: I confirm that the details of this study have been explained to the subject, in particular the possible risks and benefits of participating in this study.

Investigator Signature: Date: _ _ _ _ _

Investigator's Work Phone: Mobile phone number:

Technical specifications for the design of the informed consent form

First, the design basis

According to the Declaration of Helsinki, the International Ethical Guidelines for Human Biomedical Research issued by the Committee of International Medical Sciences Organizations (CIOMS), the SFDA Good Practice for Clinical Trials of Drugs, and clinical trial protocols.

Second, the design principle

In line with the principles of "fully informed", "fully understood", and "self-chosen". Use words and language that the subject can understand. The informed consent form should not contain text that requires or implies that the subject waives their right to compensation, or that the investigator's negligence or technical defect must be demonstrated in order to claim free medical treatment or compensation.

3. Informed consent form

Header and footer: The name of the trial project is on the left side of the header, and the date of the informed consent version is on the right. The footer is the current page number and the total page number.

The informed consent form is divided into two parts: "informed" and "consent", the former is "informed notification" (if necessary, audio-visual materials should be designed to help the subject understand the purpose, procedures, risks and benefits of the study), and the latter is "consent signature".

Two types of informed consent must be obtained before clinical trials are required for screening examinations and collection of biological specimens, one for the collection and analysis of biological specimens, and the other for participation in the trial after satisfactory laboratory results and meeting the inclusion criteria. Subjects found to be unqualified (for medical reasons) at screening should be given helpful advice, any necessary and useful treatment, or referred to other departments.

The informed consent form was given in duplicate, and the subject kept a copy of the informed consent form.

Fourth, the content of "informed notification".

Background and objectives; who should not participate in the study; other alternative treatments; What will be required if participating in the study (including study procedures, treatment regimens given, notification of possible assignment to different groups of the trial, procedures to be checked, and what will require the participant's cooperation); Based on the

experience and results of the trial, the expected possible benefits of the subject, the possible risks and inconveniences, and the medical treatment and compensation for the study-related injuries are extrapolated; the cost of the test; confidentiality of personal information; how to get more information; The principle of voluntary participation in the study, the right to withdraw from the study at any stage of the trial at any time without discrimination or retaliation, and their medical treatment and rights will not be affected.

5. The content of "consent to sign".

Declaration: The subject declares that he has read the relevant research materials, all questions have been satisfactorily answered, and that he fully understands the information about the medical research and the possible risks and benefits of the research; Confirm that sufficient time has been given for consideration; Knowing that participation in the study is voluntary, and that you have the right to withdraw from the study at any time without discrimination or retaliation, and that your medical treatment and rights will not be affected; Agree to the drug regulatory department, the ethics committee or the sponsor to access the research data. Indicates voluntary participation in the study. The investigator declares that it has conscientiously fulfilled its obligation to be informed, explaining to the participants the details of the trial, including its rights and possible benefits and risks.

Signature item: Investigator who performs informed consent, subject must personally sign and date the informed consent form. For subjects who are unable to express consent, the consent of their legal guardian should be obtained, signed and dated.

The physician performing the informed consent process or the physician designated by the research team must leave his or her mobile phone number to the subject to guarantee that the questions raised by the subject or the request of the subject are answered at any time.