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A Systematic Evaluation of the Safety of Platelet-rich Plasma (PRP) in the Treatment of Osteoarthritis

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Preface

This document is drafted in accordance with the provisionss of GB/T 1.1-2020 “Directives for Standardization - Part 1: Rules for the Structure and Drafting of Standardization Documents”.

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1. Scope

This document specifies the terms and definitions, basic principles, general requirements, safety evaluation indicators, safety evaluation methods, safety evaluation processes, and the content and format of evaluation reports for the systematic evaluation of the safety of platelet-rich plasma (PRP) treatment for osteoarthritis.

This document is applicable to the systematic clinical safety evaluation of PRP treatment for patients with osteoarthritis caused by degenerative diseases in orthopedic and joint surgery departments of general hospitals.

2. Normative references

The content in the following documents constitutes essential provisionss of this document through normative references in the text. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

(1) T/ZGCIT XXX Technical Specification for the Preparation of Platelet-Rich Plasma (PRP)
(2) T/ZGCIT XXX Specification for Quality Control and Release Testing of Platelet-Rich Plasma (PRP)
(3) T/ZGCIT XXX Clinical Application Guideline for the Treatment of Osteoarthritis with Platelet-Rich Plasma (PRP)
(4) “Good Manufacturing Practice for Pharmaceutical Products”
(5) “Expert Consensus on the Clinical Application of Platelet-Rich Plasma in Orthopedic Surgery” (2018 Edition)
(6) “Expert Consensus on the Preparation Technique of Autologous Platelet-Rich Plasma (PRP)” (2021 Edition)

3. Terms and definitions

The following terms and definitions are applicable to this document.

(1) Platelet-Rich Plasma (PRP): A platelet concentrate extracted from autologous blood by centrifugation.
(2) Osteoarthritis (OA): Also known as osteoarthropathy, degenerative arthritis, hypertrophic arthritis, or senile arthritis, it is a chronic joint disease characterized by degenerative changes in articular cartilage and secondary bone hyperplasia, with an unclear etiology.
(3) Safety Evaluation: The process of systematically monitoring, evaluating, and analyzing potential adverse reactions, adverse events, and their potential impacts on patient health during the clinical application of a specific treatment method, to determine the safety characteristics and risk level of the treatment.

4. Basic principles

4.1. Principle of comprehensiveness

The safety evaluation of PRP treatment for osteoarthritis should cover the entire process from patient selection, pre-treatment preparation, treatment implementation to post-treatment follow-up, comprehensively monitoring various potential adverse reactions and safety events to ensure no critical information is missed.

4.2. Principle of comprehensiveness

This should include the following aspects:

(1) Comprehensive consideration of individual factors such as age, gender, underlying diseases, and genetic background;
(2) PRP preparation parameters such as platelet concentration, activation method, and anticoagulant use;
(3) Details of treatment operations such as injection site, injection dose, and injection frequency;
(4) External environmental factors such as the sanitary conditions of the treatment institution and the professional skills of the operators.

4.3. Principle of dynamism

As the efficacy and safety of PRP treatment for osteoarthritis may change over time, a dynamic evaluation mechanism should be established to monitor and evaluate corresponding safety indicators at different time points (such as immediately after treatment, short-term follow-up, medium-term follow-up, and long-term follow-up), to timely detect potential delayed adverse reactions and long-term safety issues.

4.4. Principle of ethics

During the safety evaluation process, medical ethics principles should be strictly followed, fully respecting patients' rights to informed consent, privacy, and autonomous choice.

5. General requirements

5.1. Product quality

The product quality should comply with T/ZGCIT XXX "Specification for Quality Control and Release Testing of Platelet-Rich Plasma (PRP)".

5.2. Treatment process

It should comply with the requirements of T/ZGCIT XXX "Clinical Application Guideline for the Treatment of Osteoarthritis with Platelet-Rich Plasma (PRP)".

5.3. Institutional requirements

5.3.1. Legal qualification and practice license

The institution should have legal qualifications and a practice license that comply with local laws and regulations, to ensure its legal operation in the medical field.

5.3.2. Equipped with corresponding medical equipment and facilities

The institution should have relevant medical equipment and advanced laboratory facilities suitable for PRP treatment, which should comply with the relevant requirements of the "Good Manufacturing Practice for Pharmaceutical Products".

5.3.3. Equipped with a professional medical team

It should include orthopedic surgeons, PRP experts, nursing staff, etc., who should have professional knowledge and clinical experience in related fields, to effectively carry out PRP treatment.

5.4. Personnel requirements

5.4.1. Medical background and professional qualification

Medical personnel should have a relevant medical background, usually requiring a medical degree or other medical professionals such as orthopedic surgeons.

5.4.2. Professional knowledge and skills

Medical personnel should have professional knowledge and skills in related fields, especially in the treatment of osteoarthritis and PRP therapy, as well as professional skills in aseptic techniques and joint injection techniques.

5.4.3. Familiar with the principles and techniques of PRP treatment

Medical personnel should be familiar with the principles, methods, and techniques of PRP treatment, including the extraction, culture, identification, and infusion processes of PRP.

5.4.4. Familiar with clinical practice guidelines

Medical personnel should be familiar with clinical practice guidelines and the latest research results related to PRP treatment for osteoarthritis, to ensure the scientific and reliable treatment.

5.4.5. Strict patient screening and evaluation ability

Medical personnel should have the ability to strictly screen and evaluate patients, to ensure that the treatment is suitable for patients who meet the corresponding criteria, while excluding cases with contraindications.

5.4.6. Communication skills and maintenance of doctor-patient relationship

Medical personnel should have good communication skills, be able to establish trust and cooperation with patients, and fully explain the treatment process, potential effects, and risks.

5.4.7. Compliance with medical ethical principles

Medical personnel should comply with medical ethical principles during PRP treatment to protect patients' rights and safety.

5.4.8. Continuous education and training

Medical personnel should participate in continuous education and training, keep track of the latest medical research achievements and clinical practices, and maintain professional standards in this field.

5.4.9. Emergency response capability

Medical personnel should have the ability to respond to unexpected situations and complications that may occur during the treatment process, and be able to quickly make correct emergency responses.

6. Safety evaluation indicators

6.1. Local adverse reaction indicators

6.1.1. Pain

Standardized pain assessment tools such as the Visual Analog Scale (VAS) or Numeric Rating Scale (NRS) should be used to record changes in the degree, nature, frequency, and duration of joint pain before, during, and after treatment, as well as during follow-up. Abnormal conditions such as increased pain or new pain should be identified, and their correlation with treatment should be analyzed.

6.1.2. Swelling

The degree of swelling should be evaluated by measuring joint circumference or observing local joint appearance (such as skin tension, color, and texture). The time of swelling occurrence, resolution, and whether it is accompanied by other symptoms such as pain and fever should be recorded to determine whether the swelling is a treatment-related adverse reaction.

6.1.3. Erythema

Observe whether there is erythema around the joint, including its range, color, and boundary clarity. Determine whether it is a manifestation of allergic reaction or inflammatory reaction, and record the duration and resolution process of the erythema.

6.1.4. Joint effusion

Methods such as ultrasound, MRI, or joint puncture should be used to detect the formation of effusion in the joint cavity. Evaluate the amount and nature of the effusion (such as clear, bloody, purulent, etc.) and its impact on joint function. Analyze the causal relationship between joint effusion and PRP treatment.

6.1.5. Local infection

Closely observe the presence of infection symptoms and signs such as redness, swelling, heat, pain, and suppuration at the treatment site. Regularly perform wound secretion culture and drug sensitivity tests. Once an infection is detected, effective anti-infection measures should be taken promptly, and the occurrence, development, and treatment results of the infection should be recorded in detail.

6.1.6. Local reactions related to joint surgical operations

When applied in the field of joint surgery, such as in combination with arthroscopic surgery, open surgery, and PRP treatment, additional attention should be paid to the healing of the surgical site. Record wound healing time, presence of dehiscence, bleeding, and drainage. Observe redness, swelling, induration formation, and scar hyperplasia around the surgical incision.

6.2. Systemic adverse reaction indicators

6.2.1. Fever

Monitor changes in patients' body temperature and record the degree of fever (low-grade, moderate, high), duration, fever pattern (such as continuous, remittent, intermittent), and accompanying symptoms (such as chills, headache, fatigue). Determine whether the fever is related to the immune response or infection after PRP treatment, and take appropriate measures to reduce the temperature.

6.2.2. Allergic reactions

Observe patients for allergic symptoms and signs such as skin itching, rash, urticaria, dyspnea, and blood pressure drop. Inquire about the patient's past history of allergies. For patients with suspected allergic reactions, allergen detection and corresponding anti-allergic treatment should be performed promptly, and the occurrence and severity of allergic reactions should be recorded in detail.

6.2.3. Gastrointestinal reactions

Inquire about gastrointestinal discomfort symptoms such as nausea, vomiting, abdominal pain, and diarrhea. Understand their frequency, severity, and relationship with diet and medication use. Evaluate whether gastrointestinal reactions affect patients' nutritional intake and quality of life, and take appropriate symptomatic treatment measures.

6.2.4. Abnormal blood system indicators

Regularly perform hematological tests such as blood routine and coagulation function before and after treatment. Monitor changes in indicators such as platelet count, white blood cell count, erythrocyte sedimentation rate, prothrombin time, and activated partial thromboplastin time. Timely detect possible adverse reactions in the blood system, such as abnormal platelet aggregation, increased bleeding tendency, or thrombosis. Adjust the treatment plan or take appropriate intervention measures based on the test results.

6.2.5. Abnormal liver and kidney function indicators

Test patients' liver function (such as alanine aminotransferase, aspartate aminotransferase, bilirubin, albumin, globulin, etc.) and kidney function (such as creatinine, urea nitrogen, uric acid, etc.) indicators. Observe the dynamic changes of these indicators before and after treatment to evaluate the potential impact of PRP treatment on liver and kidney function. For patients with liver and kidney function damage, further identify the cause and provide corresponding liver and kidney protection treatment.

6.3. Long-term safety indicators

6.3.1. Risk of tumorigenesis

Conduct long-term follow-up on patients with osteoarthritis undergoing PRP therapy, documenting the occurrence of neoplastic diseases during this period, including tumor type, location, diagnosis time, and other relevant epidemiological data. Analyze the potential association between PRP treatment and tumorigenesis, taking care to exclude the influence of other confounding factors.

6.3.2. Long-term changes in joint structure and function

Evaluate long-term structural changes such as joint cartilage wear, bone hyperplasia, joint space narrowing, and

functional changes like joint mobility, stability, and muscle strength through periodic imaging examinations (X-ray, CT, MRI) and joint function assessment scales (e.g., WOMAC score, Lequesne index). Determine whether PRP treatment has any adverse effects on the long-term structure and function of joints, providing a basis for further optimizing treatment plans.

6.4. Adverse event management

The handling of adverse events should comply with the requirements of T/ZGCIT XXX "Guidelines for the Clinical Application of Platelet-Rich Plasma (PRP) in the Treatment of Osteoarthritis."

7. Safety evaluation methods

7.1. Clinical observation method

Trained healthcare professionals should conduct detailed physical examinations of patients before and after treatment and during follow-up, focusing on observing symptoms and signs of various local and systemic adverse reactions mentioned in the safety evaluation indicators. They should accurately and promptly record observations and classify the severity of adverse reactions (e.g., mild, moderate, severe) according to predetermined criteria for appropriate management and statistical analysis.

During each follow-up, inquire about the patient's subjective experiences since the last visit, including abnormalities such as pain, swelling, fever, discomfort, and their impact on daily life and work. Encourage patients to report any potential treatment-related adverse reactions honestly, and combine these with objective examination results to comprehensively assess the patient's safety status.

7.2. Laboratory examination method

Based on safety evaluation indicators, collect patient samples such as blood and synovial fluid at specific time points before and after treatment (e.g., 1 day, 1 week, 1 month, 3 months, 6 months, 1 year post-treatment). Send these to the laboratory for relevant tests, including blood routine, coagulation function, liver and kidney function, inflammatory markers (e.g., C-reactive protein, erythrocyte sedimentation rate), immunological markers (e.g., immunoglobulins, complement), and pathogen detection (e.g., bacterial culture, viral nucleic acid testing). Ensure the accuracy and reliability of laboratory results and promptly feedback any abnormalities to clinicians for further diagnosis and management.

For patients with joint effusion, besides routine physical and chemical analysis and cytology, special pathogen detection (e.g., tuberculin smear and culture, fungal culture) and biomarker testing (e.g., matrix metalloproteinases, cytokines) should be performed based on the patient's condition. This clarifies the etiology and nature of the effusion, providing a basis for targeted treatment plans.

7.3. Imaging examination method

During pre-treatment and follow-up, select appropriate imaging methods like X-ray, CT, MRI, or joint ultrasonography based on the patient's specific conditions to evaluate the treated joint. Focus on observing morphological and signal changes in structures such as articular cartilage, bone, synovium, meniscus, and surrounding soft tissues. Determine if there are any imaging abnormalities related to treatment, such as aggravated cartilage damage, bone destruction, synovial thickening, increased joint effusion, soft tissue swelling or calcification. Combine these findings with clinical symptoms and signs for comprehensive analysis,

assessing the impact of these imaging changes on joint function and quality of life.

Imaging examinations should be interpreted and diagnosed by experienced professional radiologists. Establish a standardized imaging report template, detailing any observed abnormalities and making an initial judgment on their correlation with PRP treatment. This provides accurate imaging information support to clinicians for timely treatment adjustments or interventions.

7.4. Patient-reported outcomes (PRO) survey method

Utilize validated PRO scales such as the Visual Analog Scale (VAS) for pain, the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), and the Short Form-36 (SF-36) health survey. Conduct questionnaire surveys at various follow-up time points before and after treatment to understand patients' subjective perceptions and evaluations regarding their health status, joint pain, functional limitations, and quality of life. Obtain information on treatment safety and efficacy from the patient's perspective.

During the PRO survey process, ensure questionnaire distribution, completion, and collection comply with standard requirements. Explain the questionnaire completion method and precautions to patients, guaranteeing they can express their feelings and experiences truthfully and accurately. Simultaneously, perform strict quality control and data analysis on collected questionnaires, integrating patient-reported outcomes with clinical observations, laboratory examinations, and imaging results for a comprehensive understanding of the safety of PRP treatment for osteoarthritis and its impact on patients' quality of life.

8. Safety evaluation process

8.1. Pre-treatment assessment

8.1.1. Patient selection

It should comply with the requirements of T/ZGCIT XXX "Guidelines for the Clinical Application of Platelet-Rich Plasma (PRP) in the Treatment of Osteoarthritis."

8.1.2. PRP preparation evaluation

It should conform to the provisionss of T/ZGCIT XXX "Technical Specification for the Preparation of Platelet-Rich Plasma (PRP)."

8.1.3. Informed consent

Fully inform patients about the purpose, methods, expected effects, possible adverse reactions, and risks of PRP treatment for osteoarthritis. Ensure that patients sign the informed consent form based on a thorough understanding, protecting their right to information and choice. This also establishes a solid foundation of communication and trust for subsequent safety evaluations.

8.2. Treatment process monitoring

8.2.1. Treatment operation records

During the PRP injection process, detailed records should be kept of the specific operational steps, including sterilization methods for the injection site, injection routes (such as intra-articular injection, peri-articular soft tissue injection, etc.), injection dose, injection speed, and patient reactions during injection. This ensures the standardization and normalization of treatment operations and provides a basis for analyzing possible

relationships between adverse reactions and treatment procedures.

8.2.2. Immediate adverse reaction observation

After the injection, closely monitor the patient's immediate reactions at the treatment site, including symptoms such as increased pain, dizziness, palpitations, sweating, rash, and dyspnea. The observation should continue for at least 30 minutes. If any abnormalities occur, prompt emergency measures should be taken, and detailed records should be made of the adverse reaction's occurrence time, manifestations, severity, and management process.

8.3. Post-treatment follow-up evaluation

8.3.1. Follow-up plan development

Based on the characteristics of PRP treatment for osteoarthritis and the requirements of safety evaluation indicators, a detailed follow-up plan should be developed. This plan should clarify the follow-up time points (e.g., 1 day, 1 week, 2 weeks, 1 month, 3 months, 6 months, 1 year post-treatment), follow-up contents (including clinical symptom inquiry, physical examination, laboratory tests, imaging examinations, etc.), and follow-up methods (such as outpatient follow-up, telephone follow-up, online follow-up, etc.). This ensures comprehensive and systematic monitoring and evaluation of the patient's condition after treatment.

8.3.2. Data collection and organization

During each follow-up, collect various safety evaluation data from patients according to the predetermined follow-up content. This includes patient subjective feelings, clinical examination results, laboratory test reports, and imaging examination images. Ensure detailed recording and organization of the data, guaranteeing its completeness, accuracy, and timeliness. This provides a reliable foundation for subsequent data analysis and safety evaluation.

8.3.3. Safety evaluation and reporting

Based on the collected follow-up data, conduct a comprehensive evaluation of the patient's safety status at each follow-up time point according to the safety evaluation index system and methods specified in this standard. Determine the presence of adverse reactions, as well as their types, severity, frequency of occurrence, and prognosis. Regularly prepare safety evaluation reports, summarizing the results of PRP treatment for osteoarthritis and providing timely feedback to clinicians and relevant researchers. These reports serve as reference points for clinical decision-making and scientific research. For cases with severe adverse reactions, conduct detailed individual case analyses and reports, deeply exploring the mechanisms and possible risk factors of adverse reactions, and proposing corresponding prevention and management suggestions to improve the safety and effectiveness of PRP treatment.

9. Contents and format of the safety evaluation report

9.1.1. Basic information

Include the patient's name, gender, age, contact information, hospital admission number (or outpatient number), diagnosis (specific site and staging of osteoarthritis), and treatment time. This clarifies the patient's individual

characteristics and treatment background.

9.1.2. Treatment plan

Provide a detailed description of the PRP preparation method (such as the centrifugation technique used, type of anticoagulant, activation method, final platelet concentration, etc.), treatment operation process (including injection site, injection dose, injection frequency, whether combined with other treatment measures, etc.), and any special situations during the treatment (such as whether the treatment process was smooth or if any unexpected events occurred). This allows readers to clearly understand the specific treatment plan received by the patient.

9.1.3. Results of safety evaluation indicators

(1) Local adverse reactions

List the occurrence of adverse reactions such as pain, swelling, erythema, joint effusion, and local infection. Include information on the time of occurrence, duration, severity (described as mild, moderate, or severe), management measures (such as drug treatment, physical therapy, surgical intervention, etc.), and prognosis (such as complete resolution, partial resolution, no resolution or worsening). If relevant images or imaging data are available, annotate and explain their acquisition time and method. (2) Systemic adverse reactions

Report the occurrence of systemic adverse reactions such as fever, allergic reactions, gastrointestinal reactions, abnormalities in blood system indicators, and abnormalities in liver and kidney function indicators. Record the specific manifestations, time of occurrence, severity, diagnostic basis (e.g., laboratory test results, clinical manifestation characteristics, etc.), treatment process, and prognosis of each adverse reaction. For severe adverse reactions requiring hospitalization or special examinations, provide detailed medical records and examination report summaries.

(3) Long-term safety indicators

Summarize the monitoring results of tumor occurrence risk and long-term changes in joint structure and function. Include information on follow-up time, whether tumor cases were detected during the follow-up period (if so, describe the tumor diagnosis process, pathological type, treatment situation, etc.), and dynamic changes in joint imaging examinations and functional scoring scales. Analyze the potential relationship between these long-term safety indicators and PRP treatment, discussing and providing an outlook based on existing literature.

9.1.4. Conclusion and recommendations

Based on the safety evaluation results, make an overall evaluation of the safety of PRP treatment for the osteoarthritis patient in this case. Clarify whether severe adverse reactions occurred during the treatment process and the extent of their impact on the patient's health. Provide suggestions for subsequent treatment and follow-up for this patient. Additionally, discuss general safety issues of PRP treatment for osteoarthritis, summarizing lessons learned and providing reference points and improvement directions for future clinical practice and research work.

9.2. Report format

The format for the safety evaluation report of platelet-rich plasma in the treatment of osteoarthritis is as follows:

(1) Cover page

The cover should include the report title (e.g., "Safety Evaluation Report of Platelet-Rich Plasma in the Treatment of Osteoarthritis"), the patient's name, the report date, the name of the reporting institution, and contact information. The format should be concise and clear, facilitating easy identification and archiving.

(2) Table of contents

List the main sections and corresponding page numbers of the report to allow readers to quickly locate the desired information.

(3) Main text

The main text should elaborate on each section in the order specified above. The language should be clear, accurate, and concise, avoiding overly complex or ambiguous vocabulary and sentence structures. For data and results, visual aids such as tables, bar charts, line graphs, and flowcharts should be used to enhance readability and persuasiveness. Additionally, appropriate references should be cited in the text to support the scientific validity and reliability of the conclusions.

(4) References

List all references cited in the report, formatted according to the national standard for citation (e.g., GB/T 7714-2015). Ensure the completeness and accuracy of reference information to facilitate further reading and traceability of relevant literature.

10. Application and feedback of evaluation results

Provide timely feedback of safety evaluation results to clinicians, serving as an important reference for developing individualized PRP treatment plans for osteoarthritis. For patients with higher safety profiles, clinicians can appropriately adjust treatment parameters (such as increasing injection dose, shortening injection intervals, etc.) based on the patient's condition to improve treatment effectiveness. For patients who experience adverse reactions, clinicians should promptly adjust the treatment plan (such as suspending treatment, changing the treatment method, providing corresponding symptomatic treatment measures, etc.) based on the severity and type of adverse reaction to ensure patient safety and health.

Regularly summarize and analyze the safety evaluation results of PRP treatment for osteoarthritis in clinical practice.

Disclosure statement

The author declares no conflict of interest.

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