Informed Consent Form

Study Title: Efficacy and Safety Evaluation of Palmitoleic Acid in the Prevention of Pressure Injuries

Protocol Number:

Informed Consent Form Version: 2.0, Date: December 8, 2025

Research Institution: Shanghai Jiao Tong University School of Medicine Affiliated Ruijin Hospital

Principal Investigator(s): Zheng Jie, Yuan Yongyong

You are being invited to participate in a clinical research study. This informed consent form provides you with information to help you decide whether to participate. Please read it carefully, and if you have any questions, please direct them to the investigator in charge of this study.

What is the background and purpose of the study?

Pressure Injury (PI), also known as a pressure ulcer or decubitus ulcer, is a pathological process where local tissue ischemia and hypoxia, caused by pressure or a combination of pressure and shear forces on the skin and underlying soft tissue, leads to tissue damage. Clinical manifestations range from localized tissue damage with intact skin to open ulcers, often accompanied by severe pain. In recent years, the incidence of PI has been increasing, with a global prevalence of 12.8% among hospitalized adult patients. PI is a major cause of prolonged hospital stays, reduced quality of life, and increased mortality and healthcare costs.

Current PI prevention strategies primarily include clinical risk assessment, repositioning, pressure-relieving devices, and nutritional support. However, these measures often only delay ulcer progression without fundamentally solving the problem. Existing therapeutic or preventive strategies for PI show unsatisfactory clinical efficacy, and PI incidence remains high, partly due to limited understanding of its underlying mechanisms. To date, ischemia-reperfusion (I/R) injury is considered a primary determinant in PI formation. I/R injury refers to cellular damage caused by the restoration of blood flow to previously ischemic and hypoxic tissues. This process may cause extensive cellular damage by activating leukocytes and inducing oxidative stress. Therefore, interventions targeting this mechanism, particularly mitigating I/R injury through antioxidant and anti-inflammatory pathways, are considered potential strategies to overcome current PI prevention challenges.

Palmitoleic Acid (POA) is an ω-7 monounsaturated fatty acid that has recently gained attention for its significant biological activities, including anti-inflammatory, antioxidant, and tissue repair-promoting effects. Basic research suggests that POA may have a potential protective effect against I/R injury by modulating inflammatory factor expression and reducing oxidative stress. However, these valuable findings have not been fully translated and validated in the clinical practice of PI prevention. High-quality clinical evidence regarding the efficacy and safety of topical POA application for PI prevention remains lacking.

In summary, facing the severe clinical challenges and high socioeconomic burden posed by PI, there is an urgent need to explore and validate novel, targeted preventive strategies based on a deeper understanding of its core mechanism—I/R injury. This study aims to

evaluate the clinical efficacy and safety of topical Palmitoleic Acid application in preventing PI. It not only holds the potential to provide an innovative intervention for PI prevention but will also offer valuable clinical evidence for understanding the role of fatty acids in tissue protection.

If I participate, what will I be required to do?

This study plans to enroll 60 patients.

If you agree to participate, you will be assigned a study number, and a medical record file will be created. You will receive the unified intervention, and comparisons will be made before and after the intervention.

During the screening phase, we will use instruments to assess your risk of pressure injury and take photographs for documentation. You only need to assume the appropriate position as required for the assessment. During the product application phase, researchers will apply the product for you at 8:00 AM, 12:00 PM, 4:00 PM, and 8:00 PM daily, and take daily photographs of the application site's skin condition. Every week, researchers will use instruments to assess the efficacy and take photographs. Again, you only need to assume the appropriate position as required. The entire study lasts a maximum of 2 weeks and will be conducted during your hospitalization. Assessments with instruments will also be required on the day before discharge or the last day of the second week.

If you experience any discomfort during the study, you should contact your research doctor at any time.

Are there any risks involved in the study?

The test product involved in this study has undergone patch testing by Shanghai Jiyan Cosmetics Technology Co., Ltd. However, as with the use of any other care product, due to individual differences among subjects, possible adverse reactions may include allergic reactions such as erythema, wheals, or urticaria on the skin.

We will diligently follow up, monitor, and record any adverse reactions related to the study product and/or your medical condition, such as contact dermatitis. If any known or currently unknown adverse reactions caused by the study product occur, please promptly contact your doctor or the investigator listed in this consent form. The physician will provide you with active treatment in accordance with medical standards.

What are the potential benefits of participating?

If you agree to participate in this test, you will receive the test product and any related assessments free of charge, as well as benefit from professional dermatologist consultations. Additionally, your participation is of great significance to us in evaluating the research and development of this test product.

Are there any costs or compensation for participation?

Costs: The costs of the test product and related assessments are covered by the research funds.

Compensation: None.

What happens if I am harmed as a result of participation?

If you experience an adverse reaction during the testing process that is caused by the test or the test product, and it is determined by the hospital to be related to this study, you will receive full compensation. Furthermore, the study sponsor will ensure that you receive free medical treatment and will provide corresponding compensation in accordance with

relevant laws and regulations.

Will my information be kept confidential?

If you decide to participate in this study, your participation and all personal data obtained during the research will be kept confidential. Your biological specimens will be identified by a research code number, not by your name. Information that could identify you will not be disclosed to anyone outside the research team unless required by law or with your permission. All research team members and the study sponsor are required to maintain the confidentiality of your identity. Your records will be kept in a locked file cabinet, accessible only to the research personnel. To ensure the study is conducted in compliance with regulations, authorized representatives of government regulatory agencies or the ethics review board may inspect your records at the research site as required. When the results of this research are published, no information that could personally identify you will be disclosed. All recorded photographs involving the head and face will undergo image masking.

Am I required to participate?

Your participation is voluntary. You may choose to participate or not. You may also withdraw from the study at any time by notifying the investigator. If you withdraw, your data will not be included in the research results, and your medical care and rights will not be affected in any way.

The research physician may discontinue your participation in this study if you require other treatments, if you do not follow the research plan, if a study-related injury occurs, or if continuing participation might otherwise increase the risk of harm to you.

Who can I contact for more information?

You may inquire about information related to this study and its progress at any time. If new safety information related to this study becomes available, we will also notify you promptly. If you have questions related to this study, experience any discomfort or injury during the study, or have questions concerning your rights as a participant, you may contact Yuan Yongyong at 18917762651.

This study has been reviewed and approved by the **Human Research Ethics Committee of Ruijin Hospital Affiliated to Shanghai Jiao Tong University School of Medicine**. If you have any questions or concerns regarding your rights and welfare as a research participant, you may contact the Institutional Ethics Committee at Tel: 64370045-675226; Contact Person: Ms. Zhao.

Informed Consent Signature Page

I have read this informed consent form.
I have had the opportunity to ask questions, and all questions have been answered to my satisfaction.
I understand that participation in this study is voluntary.
I understand that I can voluntarily choose to participate or not participate in this study, or withdraw at any time by notifying the investigator without facing discrimination or retaliation. My medical treatment and rights will not be affected as a result.
I understand that the research physician may discontinue my participation in this study if I require other treatments, if I do not follow the research plan, if a study-related injury occurs, or if continuing participation might otherwise increase the risk of harm to me.
I will receive a signed copy of this "Informed Consent Form."
Participant's Name: _____
Participant's Signature: _____
Date: _____ Year _____ Month _____ Day

Legal Representative's Name: _____
Legal Representative's Signature: _____
Date: _____ Year _____ Month _____ Day

Guardian's Name: _____
Guardian's Signature: _____
Date: _____ Year _____ Month _____ Day

Witness's Name: _____
Witness's Signature: _____
Date: _____ Year _____ Month _____ Day

(*Note: A witness signature is required if the participant is illiterate. A legal representative's signature is required if the participant lacks legal capacity or has limited legal capacity.*)

I have accurately presented this document to the participant, asked him/her to read this informed consent form carefully, and have provided satisfactory answers to all questions or concerns raised.
Investigator's Name: _____
Investigator's Signature: _____
Date: _____ Year _____ Month _____ Day