Informed Consent Form for the Study on the Safety and Efficacy of High-Intensity Macrofocused Ultrasound for Solar Lentigo in Chinese Population: A Prospective Study

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Dear Sir/Madam,

We invite you to participate in a research study titled "Safety and Efficacy of High-Intensity Macrofocused Ultrasound for Solar Lentigo in Chinese Population: A Prospective Study". This study has been approved by the Ethics Committee of the First Affiliated Hospital of Nanjing Medical University (Jiangsu Province Hospital), with an ethical approval number: No. 2023-SR-708. The study will be conducted at Jiangsu Province Hospital, with an estimated enrollment of 20-30 voluntary participants.

Purpose of the Study

Solar lentigo, also known as age spots, is a form of skin disorder related to photoaging. They mainly appear as irregular gray or dark brown patches on sun-exposed areas like the face, neck, and hands, which can affect appearance and cause psychological stress. Current treatments include laser, cryotherapy, chemical peeling, and medications. Laser treatments like Q-switched laser therapy are considered effective but may cause discomfort, redness, and hyperpigmentation, especially in individuals with darker skin.

High-Intensity Focused Ultrasound (HIFU) is a technique that uses focused ultrasound to stimulate collagen regeneration and remodeling in the skin. Both micro- and macro-focused ultrasound have proven to be effective non-invasive treatments for skin rejuvenation. Studies have proven the potential of HIFU in reducing melanin without being influenced by skin color, potentially minimizing side effects. This study aims to evaluate the efficacy and safety of high-intensity macro-focused ultrasound in the treatment of facial solar lentigo, as well as its other effects on skin by subjective and objective methods.

Who Should (and Should Not) Participate in the Study?

Inclusion Criteria:

1.adults between 18 and 70 years old, regardless of gender;

2.those who comply the clinical diagnostic criteria for solar lentigo on both sides of the face;

3.patients understand and are willing to participate in this clinical trial and voluntarily sign an informed consent form;

Exclusion Criteria:

1.Women who are pregnant or breastfeeding, or who plan to become pregnant during the trial period;

2.those who are allergic to medical condensation gel;

3.those with photosensitive diseases, immune deficiencies, or those who are taking immunosuppressants;

4.those with scar physique;

5.those with inflammatory or infectious skin diseases;

6.those who have systemically used retinoic acid in the last six months or topically applied retinoic acid drugs in the last three months, or have a history of sun exposure in the four weeks prior to treatment;

7.those who have undergone high-intensity focused ultrasound treatment within the last six months;

Procedure Overview

Before the treatment, a 2-3mm layer of medical cooling gel will be evenly applied to your face. The treatment involves using an ultrasound device with different focal depths of 3.0 mm (D3.0) and 4.5 mm (D4.5) (MFUS One, Hunan Peninsula Medical Technology Co., Ltd., China) on both sides of the face. After the procedure, an ice pack will be applied to the treated area for 10 minutes to help reduce redness and swelling. Follow-up visits will be scheduled at 2, 4, 6, and 8 weeks after the treatment. During these visits, clinical images and non-invasive skin assessments will be conducted to monitor your progress.

What Are the Benefits of Participating?

By participating in this study, you may experience an improvement in facial solar lentigo. Moreover, your participation could contribute to determining a safer and more effective treatment method for other patients with similar conditions.

What Are the Risks of Participating?

All treatments carry the potential for side effects. During the treatment, patients may experience varying degrees of pain and localized swelling, which are generally tolerable. A small number of patients may experience adverse reactions after treatment, such as pain, redness, edema, bruising, or purpura in the treated area. These reactions typically subside on their own within a few months. If you experience any discomfort or adverse effects, please contact the doctor promptly. Most side effects resolve within a few weeks, and using moisturizing skincare products and maintaining strict sun protection after treatment can help reduce the likelihood of adverse reactions.

Do I Have to Participate?

Participation in this study is entirely voluntary. You have the right to decline participation or withdraw from the study at any time. If you decide to withdraw from the study, please inform your doctor.

Participant's Statement:

I have read the above information regarding this study and fully understand the potential risks and benefits of participating. I voluntarily agree to participate in this study. I will receive a copy of this informed consent form, signed with my name and date.

I agree □ or refuse □ to allow the use of my medical records and clinical samples related to this study for other research purposes.

Participant's Signature: _____ Date: _____ / _____ / _____

Phone Number: _____

Investigator's Statement:

I confirm that I have provided the participant with detailed information about this study, including the potential risks and benefits of participation. I have also answered all of the participant's questions. The participant has voluntarily agreed to take part in this study. This informed consent form is prepared in duplicate, with one signed copy retained by the investigator and the other by the participant.

Investigator's Signature: _____ Date: _____ / _____ / _____

Investigator's Office Phone Number: _____