

Official Title of the Study: The Combination Therapy of Nanofat Grafting and Platelet-Rich Plasma Injection Compared with Microfat Grafting and Platelet-Rich Plasma Injection Synergy in Treating Striae Distensae.

Protocol

1、Duration of the study: 6 months of treatment with 9 months of follow-up observation.

2、Types of research: Randomized.

3、Number of cases: 12 cases.

4、Inclusion Criteria:

- The striae distensae
- Age \leq 35 years old

5、Exclusion Criteria:

- Skin allergy
- Cicatricial diathesis
- Skin inflammation or wound
- Platelet dysfunction syndrome
- Take anticoagulant drugs
- Acute or chronic infection
- Chronic liver disease
- Active vitiligo, psoriasis, systemic lupus erythematosus

6、Detailed method:

The protocol of the study was approved by the local ethics committee, and all patients read and signed written informed consent forms. Before treatment, patients will be accepted several examinations, for example: blood pressure, routine blood test, ECG, blood coagulation test, virus examination, etc. The procedure will be performed under local anesthesia.

The participants were randomly assigned into two groups. Group A is treated by nanofat grafting once every three months for 2 times combined with PRP injection once a month for 6 times. Group B will be treated by microfat grafting once every three months for 2 times combined with PRP injection once a month for 6 times.

The participants were asked to come back 1、3、6、9 months after treatment for further follow-up. Before and after the treatment, the striae distensae will be assessed subjectively by satisfaction assessment, and objectively by ultrasound and immunohistochemical analysis.

7、Possible complications: Redness and swelling、pigmentation、unknown complications, etc.

Statistical Analysis Plan

I> Therapeutic Effect

1) According to the results of ultrasound, to compare the striae changes before and after the treatments: Estimate the change of dermal thickness and width of striae after the application of nanofat or microfat grafting with PRP injection.

2) Whether nanofat or microfat grafting are effective in treating striae distensae, depends on ultrasound.

*The observation index above are analyzed by the methods of SPSS T-test and ANOVA.

II> Complications rate

According to the results of Satisfaction assessments, the complications will be noted by participants, which include the information about when the side effects happened, when it relieved, etc, and will be estimated by SPSS Chi-square test.