

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

**Date of Document:** 2017-10-21

## **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: 10 cases.

4、Inclusion Criteria:

- The striae gravidarum was appeared within 3 years
- Age  $\leq$  35 years old
- Not in lactation
- Not pregnancy within 15months

5、Exclusion Criteria:

- Skin allergy
- Skin inflammation or wound
- Platelet dysfunction syndrome
- Take anticoagulant drugs
- Acute or chronic infection
- Chronic liver disease
- Photodermatosis
- Active vitiligo, psoriasis, systemic lupus erythematosus
- Systemic disease
- Other clinical trial

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 investigator then will pick out two areas of most severe striae gravidarum on a patient's abdomen. One of the areas will be treated by fractional laser once every three months for 2 times combined with PRP injection once a month for 6 times. Another area will be treated by nanofat grafting once every three months for 2 times and PRP therapy once a month for 6 times.

The patients were asked to come back 1、3、6、9 months after treatment for further follow-up. Before and after the treatments, the striae gravidarum will be assessed subjectively by satisfaction assessment, dermatoscope and ultrasound, and objectively by 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 laser or nanofat grafting with PRP injection.

2) Whether fractional laser and nanofat grafting are effective in treating striae gravidarum, 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.