

July 15<sup>th</sup>, 2018

Title: **Role of Platelet Rich Plasma in supporting the recovery of post-partum Levator Ani Muscle trauma**

Running title: **Platelet rich plasma in levator ani muscle trauma**

NCT number: **NCT03021954**

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Financial disclaimer: **None**

## Study Analysis Plan (SAP)

- **Estimated Sample Size**

$$n1 = n2 = 2 \left( \frac{(Z\alpha + Z\beta)S}{X1 - X2} \right)^2$$

Information:

n = Number of samples

$\alpha$  = type I error is set at 5 %, the hypothesis is in the direction of  $Z\alpha = 1.64$

$\beta$  = type II error is set at 10 %, the hypothesis is in the direction of  $Z\beta = 1.28$

$X1 - X2$  = the minimum difference that is considered significant

- Measurement of the levator hiatal area during valsalva, the researchers set a value of  $X1 - X2 = 5$ . From the journal about the levator ani hiatus area during Valsalva, it was obtained  $SD = 6.09$ . The sample size for each group was 23 subjects.
- Measurement of the strength of the levator ani muscle contraction, the researchers set a value of  $X1 - X2 = 9$ . From the journal on the strength of the levator ani muscle contraction, it was obtained that  $SD = 11.63$ . The sample size for each group was 27 subjects.
- The drop out number of samples is added by 20%. Thus, the total sample is 65 people.

- **Sampling Method**

The sample was taken consecutively. The researcher took subjects who met the inclusion criteria and passed the exclusion criteria until the target number of subjects was met. Randomization using online randomizer. Subjects were divided into two groups, namely the intervention group with PRP injection and the control group.

- **Daya Analysis**

Data were analyzed using Statistical Product and Service Solutions version 20 (SPSS version 20). Univariate analysis was performed for each variable and then presented in terms of frequency and percentage. For the bivariate analysis of the intervention and control groups with certain independent variables used unpaired categorical comparative

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analysis of 2 groups using the Mann-Whitney test, paired comparative analysis of 2 groups using the Wilcoxon test. If  $p < 0.05$ , then multivariate analysis was performed.