Cover Page

Official title of the study: A Randomized Clinical Trial to Assess the Efficacy of Intrauterine Balloon Compared to Intrauterine Contraceptive Device Plus Foley Catheter in the Therapy for Uterine Adhesion After Hysteroscopic Adhesiolysis.

Date: 12/01/2017

Statistical Analysis Plan

1. Measurements used: This study was taken out to compare two mechanical devices (intrauterine balloon and Intrauterine Contraceptive Device Plus Foley Catheter) in the therapy for intrauterine adhesions after hysteroscopic adhesiolysis. The efficacy in the prevention of adhesion reformation after hysteroscopic adhesiolysis for Asherman syndrome was compared between the groups.

2. Sample size calculation: Assuming that the adhesion recurrence rate was 46% in patients with intrauterine heart-shaped balloon insertion and in the group receiving intrauterine contraceptive device (IUD) plus Foley catheter was 18%, and accepting a type 1 error (α) of 0.05, and a type 2 error (β) of 0.10, the number of subjects required was 53 in each arm. After assuming the drop-out rate of 20%, the total number of subjects required was 132.

3. Statistical methods: Data analysis was performed with SPSS

version 22.0 (SPSS, Inc., Chicago, IL, USA), using two-sided test, and a p value < 0.05 was considered statistically significant. The continuous variables were analyzed by the Student's t test. The rate of reformation adhesions were described as percentages and were evaluated using chi-squared ($\chi 2$) test or Fisher's exact test. The Mann-Whitney test was used to compare the reduction of AFS score between the groups.