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**Official Title:** Follicle Activation in Patients with Poor Ovarian Response Through Fragmentation of the Ovarian Tissue.

**ClinicalTrials.gov.ID:** NCT02354963

**Document date:** 10<sup>th</sup> April 2022

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## **Statistical Analysis Plan**

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The allocation of patients to the study groups was performed using a random number generator ([www.random.org](http://www.random.org)), the numbers generated were included in a sealed envelope that was opened at the time of patient randomization.

Information on study variables was collected in a data record booklet (DRB) designed specifically for this study. A database was created to contain the information from the CRFs of the included patients and was equipped with internal consistency rules to control for inconsistencies and/or inaccuracies in data collection and tabulation. The internal coherence rules were guaranteed based on index fields that avoid duplicate records, detect out-of-range or suspicious data and prevent the recording of unrelated data. Before the computerization of the data, a thorough review of the data CRFs was carried out to ensure maximum reliability of the record.

Statistical analysis was performed with the SPSS 2.0.0 statistical package. Variables that followed a normal distribution were expressed as mean and standard deviation, and variables that did not follow a normal distribution were described as median and range. Categorical variables were expressed as absolute values and percentages. Observed differences were considered statistically significant if  $p < 0.05$ . Comparison of quantitative variables was performed using the Student's t-test or U-Mann test, as appropriate. Comparison of categorical variables was performed using the Chi-square or Fisher test, as appropriate.