Polo per la Tutela e la Salute della Donna e della Vita Nascente
Fondazione Policlinico A. Gemelli
Università Cattolica del Sacro Cuore
Roma

Division of Gynecologic Oncology

PRODCT: **Indocyanine Green and Near-infrared fluorescence (NIRF) video endoscopic system**

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TITOLE: **INDOCYANINE GREEN AND NEAR-INFRARED VISION FOR DETECTION OF ENDOMETRIOSIS (*GRE-ENDO TRIAL*)**

PROTOCOL NUMBER: **736513. A 287 / C.E./2013**

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Statistical analysis

Normally the WLy is the gold standard to detect the endometriosis. We test the null hypothesis of identifying occult endometriotic lesions to WLy through the NIR-ICG in about 15% of patients. The sample size was calculated according to the study design by Simon, using an alpha-error of 0.05 and a beta-error of 0.95. Considering a patient dropout of approximately 10%, the study was planned to enrol at least 18 women. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy were calculated for each vision mode using standard formulas. Sensitivity was defined as the number of endometriosis who were correctly identified (true positives) divided by the total number of endometriosis (true positives + false negatives). Specificity was defined as the number of negative lesions for endometriosis who were correctly identified (true negatives) divided by the total number of negative lesions (true negatives + false positives). PPV was calculated as the number of true positives divided by the total number of positive results (true positives + false positives), and NPV was defined as the number of true negatives divided by the total number of negative results (true negatives + false negatives). Accuracy was calculated as the number of true positives plus true negatives (total number correct) divided by the total number of patients studied.

The pretest probability and post-test probability values for WLy and NIR-IGC were also calculated. The 95% confidence intervals were determined for each parameter. Sensitivity, specificity, and accuracy were compared using the McNemar test. The diagnostic performances of WLy and NIR-IGC were calculated on a per-patient as well as on a per-lesion basis considering final pathologic finding.

Receiver operating characteristic (ROC) curve analysis with 95% confidence interval (CI) was used to assess the ability of the ICG-NIR evaluation to identify patients who were most likely to have endometriosic lesion. Statistical calculations were performed using the Statistical Package for Social Sciences (Version 17.0, SPSS Inc., Chicago, IL, USA).