

**Safety and Security Evaluation of Patients Submitted to Minimally Invasive Radical
Prostatectomy**

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Study Protocol

This project aims to evaluate safety and security of patients submitted to minimally invasive radical prostatectomy, who received discharge from hospital in the same day of the surgery (Group I), on the 1st post-surgery day (Group II) and in the 2nd post-surgery day (Group III – control). The specific aims are the evaluation of fail index and factors that influence the permanence in the hospital, the satisfaction of patients, the perception of security of patient, the index of post-discharge complications and the costs related to different times of hospitalization. On randomization, those patients in Group I must match the early hospital discharge criteria defined in the study. Thus, they will be forwarded to “Casa de Apoio Madre Paulina”, where will receive nursing care until the next day when, in the morning, will be reevaluated in the ambulatory of urology from Barretos Cancer Hospital. The patients of Group II will be evaluated in the ambulatory in the 2nd postsurgery day, before the discharge. In the Group III (control), the patients will be discharged in the 2nd post-surgery day (routine of Barretos Cancer Hospital). All patients who accept to be enrolled in the study will sign the Consent Term previously the surgery. At the 10th post-surgery day, in the follow-up, it will be applied the questionnaire SATISBR and an inventory.

Statistical Analysis Plan

This project aims to evaluate safety and security of patients submitted to minimally invasive radical prostatectomy, who received discharge from hospital in the same day of the surgery (Group I), on the 1st post-surgery day (Group II) and in the 2nd post-surgery day (Group III – control). The specific aims are the evaluation of fail index and factors that influence the permanence in the hospital, the satisfaction of patients, the perception of security of patient, the index of post-discharge complications and the costs related to different times of hospitalization. On randomization, those patients in Group I must match the early hospital discharge criteria defined in the study. Thus, they will be forwarded to “Casa de Apoio Madre Paulina”, where will receive nursing care until the next day when, in the morning, will be reevaluated in the ambulatory of urology from Barretos Cancer Hospital. The patients of Group II will be evaluated in the ambulatory in the 2nd postsurgery day,

before the discharge. In the Group III (control), the patients will be discharged in the 2nd post-surgery day (routine of Barretos Cancer Hospital). All patients who accept to be enrolled in the study will sign the Consent Term previously the surgery. At the 10th post-surgery day, in the follow-up, it will be applied the questionnaire SATISBR and an inventory. The data will be descriptive considering average, standard deviation, minimum and maximum value and quartile to the quantitative variables and frequency tables to the qualitative variables. In order to determine the groups' homogeneity, some sociodemographic and clinical characteristics will be compared. To the qualitative variables, it will be used chi-squared test (of Fishers exact test), and to the quantitative variables it will be used variance analysis (or Kruskal-Wallis test). The patients' satisfaction will be measured using SATIS-BR, which consists in three numeric domains (ranging from 1 to 5). The comparison of each domain among the groups will be performed using ANOVA. Then, linear regression will be performed in order to analyze the relationship of the patients' characteristics influencing the satisfaction. The rates of fail, clinical security, security perception and post-discharge complications will be compared among the groups using chi-squared test (of Fisher's exact test). There will be considered the significance level of 5%.