Effect of dexmedetomidine combined with low-dose nalmefene on preventing remifentanil-induced postoperative hyperalgesia

NCT ID: NCT03096730

Document date :2017-2-15

Statistical analyses

The mechanical hyperalgesia threshold of the dominant inner forearm was considered the primary outcome. Based on our previous results (Zhen. Jia, Yi .Chen, and Guolin. Wang, unpublished raw data), a power analysis was implemented to calculate the sample size. The mean mechanical hyperalgesia threshold of the dominant inner forearm at baseline (the day before surgery) was 96.0 g, whereas the means of the four treatment groups (Group R, Group N, Group D, and Group DN) at 24 h after surgery were 61.5, 67.2, 73.0, and 74.0g, respectively. We determined a difference of at least 30% (error standard deviation=26.0) among the treatment groups. An a priori algorithm was used to estimate the required sample size for analysis of variance (ANOVA) with repeated measures. A sample size of 27 patients per group was found to be sufficient to detect a significant difference (α=5%) with a statistical power (β-value) of 0.8. Presuming a 10% failure rate, we considered increasing the sample size to 30 patients per group.

The Shapiro–Wilk test was used to determine the normality of

distribution of the data, and parametric statistics were applied. Homogeneity of variance was verified by the Levene test. Data from the Ramsay scores, NRS scores, and mechanical hyperalgesia threshold were analysed by two-way repeated measures with Bonferroni post hoc comparisons. Data from time and total dose of first postoperative sufentanil titration, sufentanil consumption by PCA, and normalized area were analysed by one-way with Dunnett's post hoc comparisons. Other quantitative data, such as age, weight, duration of remifentanil infusion, mean concentration of desflurane, recovery time and extubation time were also analysed using one-way with Dunnett's post hoc comparisons. Simultaneously, the $\chi 2$ test and Fisher's exact test were used to analyze categorical variables, such as phenylephrine administration, somnolence, dizziness, nausea, and vomiting. Data were expressed as the mean (SD) or number of patients (percentage). A statistically significant difference was interpreted as a P-value of <0.05. SPSS 21.0 software (SPSS, Inc., Chicago, IL, USA) was used for all statistical analysis.