11 EFFICACY EVALUATION

11.1 Efficacy results and tabulation of individual subject data

11.1.1 Primary efficacy data: proportion of subjects with a successful block

The proportion of subjects (PP set) who achieved a successful block, defined as anaesthesia adequate for the surgery, without any supplementation in the first 45 min from the time of readiness for surgery (see § 9.5.1.2), was 89/98 (90.8%) with Chloroprocaine HCl 2% and 92/99 (92.9%) with Ropivacaine HCl 0.75% (Table 14.2.1.1).

The overall proportion of subjects with a successful block (all centres) was compared between treatment groups using a binomial regression model, with the factors treatment and analysis centre as fixed effects. Results showed that non-inferiority of Chloroprocaine HCl 2% with respect to Ropivacaine HCl 0.75%, administered by axillary injection under ultrasound guidance, was confirmed (Table 14.2.1.3). In fact, the lower limit of the 95% two-sided confidence interval of the difference between the two treatments proportion of success (equivalent to the lower limit of the 97.5% one-sided confidence interval) was above the pre-established 10% non-inferiority margin (δ = -0.1). The test was statistically significant (p-value=0.0210) and the null hypothesis was rejected, consistently with the hypothesis test reported in § 9.7.19.1.

The results are summarized in the table below:

Table 11.1.1.1 Frequency of patients with a successful block - Binomial regression - PP set

Block	n (%)		LSMeans Estimates		Difference	95% CI	One-sided p-value
	Test N=98	Reference N=99	Test	Reference			
Success	89 (90.8%)	92 (92.9%)	0.885	0.914	-0.029	-0.097, 0.039	0.0210*
Failure	9 (9.2%)	7 (7.1%)	-	-	-	-	-

Source: Table 14.2.1.1 and Table 14.2.1.3; LS: Least Squares
**Statistically significant*

No effect of treatment, analysis centre or analysis centre-by-treatment was present (p-value > 0.1570; Table 14.2.1.4).

Results of the statistical analysis on the FAS (sensitivity analysis) confirmed the results obtained with the PP set (primary analysis), with 96/105 (91.4%) patients with a successful block for Chloroprocaine HCl 2% and 97/104 (93.3%) patients with a successful block for Ropivacaine HCl 0.75% (Table 14.2.1.2), and a derived 95% confidence interval of -0.091, 0039 (p-value=0.0125) (Table 14.2.1.5).

Binomial regression performed by applying the Worst case method, i.e. with primary endpoint missing values replaced as block failure or block success if patient(s) with missing values received Test or Reference treatment, respectively, also confirmed the study results (Table 14.2.1.6).