Study code: 1001-PR-PRI-133

EudraCT no.: 2005-001880-68

Study title: Standardization of Latex allergenic extract. Determination of biological activity in HEP units.

Trial results: A total of 44 patients (mean age 45,6 years) were enrolled.
A total number of 41 patients received the study medication (ITT population).
17 were excluded from the PP population since they met any of the excl. criteria and/or did not meet some of the inclusion or Nordic Guideline criteria (PP = 31).

Descriptive analysis was performed for safety, demographics, medical history, physical examination and concomitant medications in both, PP and ITT population (ITT coincided with the Safety population), but the wheal data of the 6 patients included to determine the primary variable was only analyzed in the PP population.
One ADR (AE) was observed. Immediate local and mild reaction which developed into a late phase reaction (hard arm for approximately 1 day).

Conclusions: No statistical analysis has been performed for this clinical trial, since only 14 subjects met the Nordic Guideline criteria for analysis and it requires, at least, 20 subjects fulfilling the criteria to obtain a valid result.
A total of 44 subjects consented to participate in the trial, but 1 of them was excluded for not meeting the selection criteria and another 2 subjects did not follow the protocol procedures and were not evaluable. Out of these 41 subjects meeting the eligibility criteria, 10 subjects were excluded from the statistical analysis either because the Latex allergen concentrations did not induce a wheal in 3 of them or the regression analysis could not be carried out in 7 subjects since less than 3 allergen concentrations had been tested. Out of the remaining 31 subjects, 17 did not meet the Nordic Guidelines criteria for analysis, so 14 subjects remained valid for analysis.
No conclusion has been drawn from this study because based on the Nordic Guidelines it requires at least 20 valid subjects for analysis. Additionally, the high percentage of subjects (66%) who were allergic to Latex and were not analysed for different reasons, could pose an external validity issue with the study population.
Therefore, we conclude that it is not possible to assess in vivo the biological potency of Latex allergen extract tested, in order to be used as IHRP.
The administration of the study medication by Skin Prick testing was well tolerated and safe.