STUDY:	Biological standardization of *Dactylis glomerata* allergen extract
PROTOCOL NUMBER:	6038-PR-PRI-181
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STUDY TITTLE:	Biological standardization of *Dactylis glomerata* allergen extract to determine the biological activity in HEP units.
SPONSOR:	Laboratorios LETI, S.L.Unipersonal C\ Sol, 5. 28760 Tres Cantos. Madrid. Spin Phone: +34 91.771.17.90 / Fax: +34 91.804.09.19 http://www.leti.com
TRIAL REUSLT:	A total of 31 patients (mean age 32 years) were enrolled. A total number of 31 patients received the study medication (ITT population). 5 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 = 26). 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 26 patients included to determine the primary variable was only analyzed in the PP population. 0.03 mg of Dactylis glomerata allergen extract elicited a wheal size equivalent to that of histamine 10 mg/mL. No ADRs were observed
CONCLUSIONS:	The biological activity of Dactylis glomerata allergen extract equivalent to 10 HEP/mL is obtained using 0.03 mg/mL of this allergen extract. The administration of the study medication by Skin Prick testing was well tolerated and safe