

Study code: 6057-PR-PRI-188

EudraCT no.: 2011-002096-42

Study title: Biological standardization of Ambrosia elatior allergen extract to determine the biological activity in HEP units.

Trial results: A total of 30 patients (mean age 32,5 years) were enrolled and all of them received the study medication (ITT).

A total number of 30 patients received the study medication (ITT population). 9 were excluded from the PP population after receiving the study medication since they met any of the excl. criteria and/or did not meet some of the inclusion or Nordic Guideline criteria (PP = 21).

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).

23,86 mg of Ambrosia elatior allergen extract elicited a wheal size equivalent to that of histamine 10 mg/mL.

No ADRs were observed.

Conclusions: The biological activity of Ambrosia elatior allergen extract equivalent to 10 HEP/mL is obtained using 23,86 mg/mL of this allergen extract.

The analysis of the safety data showed that the administration (Skin Prick testing) of Ambrosia elatior allergen extract at 15, 10, 1.0, 0.1 and 0.01 mg/mL together with a positive (histamine dihydrochloride) and negative control (glycerinated phenol saline solution) was well tolerated and safe.