

STUDY:	Biological Standardization of <i>Secale cereale</i> allergen extract
PROTOCOL NUMBER:	6049-PR-PRI-184
EUDRACT NUMBER:	2010-023951-27
STUDY TITLE:	Biological standardization of <i>Secale cereale</i> allergen extract to determine the biological activity in HEP units.
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TRIAL REUSLT:	<p>A total of 35 patients (mean age 31 years) were enrolled.</p> <p>A total number of 35 patients received the study medication (ITT population).</p> <p>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 = 30).</p> <p>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 30 patients included to determine the primary variable was only analyzed in the PP population.</p> <p>0,04 mg of <i>Secale cereale</i> allergen extract elicited a wheal size equivalent to that of histamine 10 mg/mL.</p> <p>No ADRs were observed.</p>
CONCLUSIONS:	<p>The biological activity of <i>Secale cereale</i> allergen extract equivalent to 10 HEP is 0,04 mg/mL of this allergen extract.</p> <p>The administration of the study medication by Skin Prick testing was well tolerated and safe.</p>