

A Randomized, Double-blind, Multicenter, Phase 111 Study to Evaluate the Efficacy and Safety of Pasireotide LAR in Patients with Cushing's Disease

Principal Investigator	Peter J. Snyder
Study Title:	Protocol Title: A Randomized, Double-blind, Multicenter, Phase 111 Study to Evaluate the Efficacy and Safety of Pasireotide LAR in Patients with Cushing's Disease
Purpose:	The purpose of this clinical research study is to find out if the drug pasireotide LAR is safe and has beneficial effects in patients who have Cushing's disease and to determine the most effective dosage.
Brief Description	<p>Cushing's disease is caused by hypercortisolism (excess levels of cortisol in your body) due to a benign tumor in the pituitary gland. The tumor produces a hormone called ACTH (adrenocorticotrope hormone) in more than normal amounts. Pasireotide LAR is a long acting formulation of pasireotide that is injected monthly. It is an investigational drug being developed by Novartis Pharmaceuticals.. Subjects must make 21 visits over a 14 month period. After a 30 day screening period, patients who meet all eligibility criteria will be randomized in a 1:1 ratio and in a double-blind manner to receive one of two pasireotide LAR regimens (starting dose of either 10 mg or 30 mg i.m.</p>
Eligibility	<p>Adult patients with confirmed diagnosis of ACTH-dependant Cushing's disease as evidenced by all of the following:</p> <ul style="list-style-type: none">a. The mean of three 24-hour urine samples collected within 2 weeks $\geq 1.5 \times$ ULN and $\leq 5 \times$ ULN (as determined by the central lab of this study)b. Morning plasma ACTH within the normal or above normal rangec. Either MRI confirmation of pituitary adenoma > 6 mm, or inferior petrosal sinus gradient >3 after CRH stimulation for those patients with a tumor less than or equal to 6 mm*. For patients who have had prior pituitary surgery, histopathology confirming an ACTH staining adenoma. <p>Patients with de novo Cushing's disease can be included only if they are not considered candidates for pituitary surgery (e.g. poor surgical candidates)</p>
Compensation (if applicable)	\$25 per visit for travel expenses.
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