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Prescribing decisions should be made based on the approved package insert in the country of prescription

Sponsor/company:	sanofi-aventis	**ClinialTrials.gov Identifier:**	NA
		Study Code:	L_8967
Generic drug name:	Amisulpride	**Date:**	21/Sep/2007

Title of the study:	L_8967: AMIRISMIND - Amisulpride and risperidone: Cognitive Dysfunction in acute and post-acute schizophrenia
Investigator(s):	Dr. Victor Pérez Solà – HOSPITAL DE LA SANTA CREU I SANT PAU, BARCELONA
Study center(s):	The study was performed in 6 Spanish hospitals: Hospital de la Santa Creu i Sant Pau (Barcelona), Hospital Provincial Rodríguez Chamorro (Zamora), Hospital Universitario Ntra. Sra. de Valme (Sevilla), Hospital General de Jerez (Jerez), Hospital Universitario San Juan de Alicante (San Juan de Alicante), Complejo Asistencial de Salud Mental (Granollers & Sant Boi de Llobregat).
Publications (reference):	NA

Study period: Date first patient enrolled: 11-aug-2004 Date last patient completed: 11-may-2005	**Phase of development:** IV

Objectives:

Primary objective

To study the differential effect on several cognitive functions of 2 atypical antipsychotics, risperidone and amisulpride, on the assumption that: both in the acute phase and post-acute phase, the effects of risperidone and amisulpride on the cognitive semiology and left schizophrenic symptomatology allow to set a characteristically therapeutically profile for each drug. Thus, cognitive semiology will be evaluated in:

a) Acute phase

b) Post-acute Phase (optional)

c) Throughout the study, if applicable (acute phase + post-acute phase)

Cognitive tests: Score of the cognitive tests WCST, WAIS-III, Block tapping test, RAVLT, trail making test and controlled word association test.

Secondary Objectives

a) Differences on the clinical effects of risperidone and amisulpride on the rest of the schizophrenic symptomatology. Thus, the following will be evaluated:

a) Acute Phase:

-Positive symptoms

-Negative symptoms

	-Affective symptoms b) Post-acute Phase (optional) -Positive symptoms -Negative symptoms -Affective symptoms c) Throughout the study, if applicable (acute phase + post-acute phase) -Positive symptoms -Negative symptoms -Affective symptoms b) Tolerability profile of both drugs.		
Methodology:	Open, randomized with two parallel groups		
Number of patients	Planned: 60	Randomized: 48	Treated: 48
Evaluated:	NA	Safety: NA	
Diagnosis and criteria for inclusion:	Hospitalized patients with schizophrenia (according to DSM-IV), in acute phase, and optionally followed in an out-of-hospital basis, 18≤age≤65 years. Women of childbearing potential must use an effective contraceptive method during the study.		
Investigational product: Dose: Administration:	Amisulpride 400-800 mg Oral		
Duration of treatment: a) Acute phase: 1 month b) Post-acute phase: 2 more months Total duration: 1-3 months	**Duration of observation:** None		
Reference therapy: Dose: Administration:	Risperidone 3-6 mg Oral		
Criteria for evaluation:	The current report is an abbreviated report. Since this study was prematurely stopped due to low inclusion rate, no analysis was done.		
Statistical methods:	At first, it was planned to analyse the clinical and cognitive scales with the corresponding parametric and non-parametric tests. In order to analyze the change in total PANSS score from baseline to final observation, the lower limit of the one-side 95% Confidence Interval was planned to be calculated. The rest of the hypotheses was planned to be calculated on the assumption of a two-sided 0.05. Since this study was prematurely stopped due to low inclusion rate, no analysis was done.		

Summary:	The primary objective of the study was to examine the differential effect on several cognitive functions of 2 atypical antipsychotics, risperidone and amisulpride in hospitalized patients with schizophrenia (according to DSM-IV), in acute phase, and optionally followed in an out-of-hospital basis. Since this study was prematurely stopped due to low inclusion rate, no analysis was done.
Date of report:	28-Aug-2007