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Sponsor/company:	sanofi-aventis	**ClinialTrials.gov Identifier:**	NCT00436371
		Study Code:	L_9517
Generic drug name:	Amisulpride	**Date:**	01/Apr/2008

Title of the study:	The use of Amisulpride in Schizophrenic Acute Phase patients (L_9517)		
Investigator(s):	Dr. Ka Fai CHUNG, Queen Mary Hospital, Pokfulam, Hong Kong. Dr. Ben CHEUNG, Rm 1710-11, Melbourne Plaza, 33 Queen's Road Central, Hong Kong. Dr. Seung Yau LEE, Kwai Chung Hospital, 3-15 Kwai Chung Hospital Road, New Territories, Hong Kong.		
Study center(s):	Queen Mary Hospital, Hong Kong Kwai Chung Hospital, Hong Kong		
Publications (reference):	N/A		
Study period: Date first **patient/subject** enrolled: 07-May-2005 Date last **patient/subject** completed: 06-Nov-2006		**Phase of development:** Phase IV	
Objectives:	Primary: To collect the safety and response of using Solian in acute schizophrenic patients Secondary: To assess patient compliance to therapy and changes in body weight at the end of 12 weeks of treatment		
Methodology:	Open-label, non-randomized, single arm, multicentre prospective drug study		
Number of patients/subjects:	Planned: 50	Randomized: NA	Treated: 50
Evaluated:	Efficacy : 50	Safety: 50	
Diagnosis and criteria for inclusion:	Patient aged 18-75 years old and diagnosed as DSM IV as paranoid, disorganized or undifferentiated type of schizophrenia in acute episode.		
Investigational product: Dose: Administration:	Amisulpride Initial dose of 400- 800mg/ day. Dose titration is allowed based on the investigators' clinical judgment Oral		
Duration of treatment: 12 weeks		**Duration of observation:** 12 weeks	
Reference therapy: Dose: Administration:	N/A N/A N/A		
Criteria for evaluation:			
Efficacy:	CGI scoring for severity of illness, efficacy index and global improvement		

Safety:	Adverse events reported by the patient/subject or noted by the investigator. Body weight measured at baseline and final visit. Compliance self-reported by patient.
Statistical methods:	No sample size calculation has been performed for this open study. Demographic and baseline data were described with continuous variables described by mean, standard deviation, range (max. and min.), and median. Categorical values were summarized by their frequency and absolute and relative percentage. The safety population included all patients exposed to at least one dose of study medication. The number of adverse events was reported as a global figure and for each category of event experienced. The drop-out rate was described both in actual figures and as a percentage of the number of patients who have not completed the study per protocol due to adverse events, lack of efficacy or loss to follow-up, versus the total number of patients included. The mean change of CGI score and body weight from baseline were described. The number of patients completing the study treatment was described in figures, and as a percentage of the total patients included. Patient compliance was tabulated based on number of missed doses by patient and investigator's assessment.
Summary:	A total of 50 patients (male: female = 1:1), suffering from schizophrenia in the acute phase, participated in the study. Of these, 31 patients completed the study as per protocol, with 19 patients withdrawing from or dropping out of the study for various reasons of which 12 were due to AEs. Among the 12 cases, 8 of them were considered related to amisulpride treatment, three being considered not related to amisulpride; and in one case the AE leading to study withdrawal being not specified.
Efficacy results: or Pharmacodynamic results:	Amisulpride use in schizophrenic patients in acute phase showed a significant change in the overall efficacy index as well as decrease in the severity of disease. Amisulpride use resulted in improvement in all the 3 CGI scores. At the end of treatment, more than half the patients (51.61%; per protocol) were responders on the CGI scale (showing 'borderline mental illness' or 'normal'). The mean CGI scores at end of 84 days of therapy for severity of illness were 2.26 compared to 4.42 at baseline. Global improvement CGI scores changed from a mean score of 3.14 at baseline to a mean score of 2.03 at the end of therapy, with 64.52% (per protocol) patients showing 'very much' or 'much' improvement. On the efficacy index, 74.19% (per protocol) patients showed marked to moderate efficacy.
Safety results:	There were 71 occurrences of adverse events (AEs) with $\geq$5% incidence, and there were 12 withdrawals from the trial due to AEs. Among the 12 cases, 8 of them were considered related to amisulpride treatment; three being considered not related to amisulpride; and in one case the AE leading to study withdrawal being not specified. Amisulpride showed a favorable safety profile with the commonest AEs being insomnia and weight gain. The mean change in body weight from baseline to the end of treatment was 2.92 kg (p=0.002). There were four serious adverse events (SAE), including one death, in which the patient had died from urinary tract infection with severe dehydration, which was considered not related to amisulpride; however, except for a case of newly diagnosed diabetes that presented with pneumonia, none of the SAEs, including death, were considered by the investigators to be related to the study drug. At the end of four weeks, only five (13.16%) patients reported missed doses, the number remaining the same till the end of trial. At the end of the trial, 13 (41.94%) of the 31 patients who reported at the last visit expressed willingness to continue amisulpride treatment.
Date of report:	01-Jan-2008