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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_8923
Generic drug name:	Valproic Acide/Valproic semisodium	**Date:**	21/Sep/2007

Title of the study:	L_8923 – DPK vs. PHE: Comparative clinical trial between i.v. formulations of valproic and phenytoin in acute seizures treatment.
Investigator(s):	Dr. Luis Jiménez Murillo – Coordinator of the Emergency Department HOSPITAL UNIVERSITARIO REINA SOFÍA, CÓRDOBA - SPAIN
Study center(s):	The study was performed in 16 out of the 46 planned sites:

Hospital Reina Sofía	Córdoba	LUIS JIMENEZ MURILLO
Hospital Virgen del Rocío	Sevilla	BASILIO SOTO ESPINOSA
Hospital Virgen de la Victoria	Málaga	PEDRO ARRIBAS SANCHEZ
Hospital Ramón y Cajal	Madrid	MARIANO AGUADO
Hospital 12 de Octubre	Madrid	EMILIO ALTED LÓPEZ
Hospital Gregorio Marañón	Madrid	FCO. JAVIER ORTIZ
Hospital La Fe	Valencia	JUAN JOSÉ VILCHEZ
Hospital Miguel Servet	Zaragoza	LUIS CASADO
Hospital Santa Creu i Sant Pau	Barcelona	JOSEP Mª GUARDIOLA
Hospital del Vall d'Hebron	Barcelona	JORDI SUMALLA
Hospital Cruces	Bilbao	GABRIEL GUTIERREZ
Hospital Juan Canalejo	A Coruña	CARMEN NOVO
Hospital do Meixoeiro	Vigo	LUIS AMADOR
Hospital de Basurto	Bilbao	JOSÉ MNEZ. DE ZÁRATE
Hospital Son Dureta	Mallorca	ANTONIO MORENO
Hospital Clínico de Valencia	Valencia	JOSÉ VICENTE BALAGUER

Publications (reference):	NA
Study period: Date first patient enrolled: 23-apr-2004	**Phase of development:** IV

Date last patient completed: 11-feb-2005			
Objectives:	Primary objective: To compare the efficacy between iv valproic acid and iv phenytoin in the treatment of acute seizures of status epilepticus at the Emergency Departments. Secondary objective: To compare the tolerability between both treatments.		
Methodology:	Open, randomized (randomization ration 1:1), two-parallel group study		
Number of patients:	Planned: 150	Randomized: 48	Treated: 46
Evaluated:	NA	Safety: NA	
Diagnosis and criteria for inclusion:	Patients suffering acute convulsive seizures or convulsive status epilepticus (convulsive defined as obvious motor activity) admitted to or treated at the Emergency Services; patients aged between 18 and 65 years.		
Investigational product: Dose: Administration:	Valproic acid 400 mg / 4 ml Intravascular bolus 15-20 mg/kg administered in 3 – 5 min, followed by a continuous infusion of Valproic Acid (1 mg/kg/h). Doses could be upgraded if it's well known that the patient is under treatment of hepathic CYP450 inductor (such as phenytoin, phenobarbital or carbamazepine). iv		
Duration of treatment: 1 day		**Duration of observation:** None	
Reference therapy: Dose: Administration:	Phenytoin 250 mg / 5 ml Intravascular bolus 18 mg/kg in 20 min + 5-7 mg/kg/24 h, 24 h later in 3-4 administrations. iv		
Criteria for evaluation:	The current report is an abbreviated report. Since this study was prematurely stopped due to very low inclusion rate, no analysis was done.		
Statistical methods:	At first, it was planned to analyze patients fulfilling protocol criteria and having been treated as per protocol (no protocol violations allowed). Data from all included patients who prematurely finish the treatment were planned to be tabulated, indicating the moment, reason of premature end (according to withdrawal data and drop-outs given by the investigator by means of the CRF) and the treatment received (diary dose, duration of participation and compliance). If deemed necessary, other relevant information were planned to be included, such as demography, concomitant medication and the result of the primary outcome. In order to analyze the effect of the premature withdrawals, time, reasons and rates wanted to be determined. Since this study was prematurely stopped due to very low inclusion rate, no analysis was done.		

Summary:	The main aim of the study was to compare the efficacy between iv valproic acid and iv phenytoin in the treatment of acute seizures of status epilepticus at the Emergency Departments. Since this study was prematurely stopped due to very low inclusion rate, no analysis was done.
Date of report:	28-Aug-2007