These results are supplied for informational purposes only.
Prescribing decisions should be made based on the approved package insert in the country of prescription

Sponsor/company:	sanofi-aventis	**ClinialTrials.gov Identifier:**	NCT00454402
		Study Code:	L_9795
Generic drug name:	Alfuzosin	**Date:**	21/Sep/2007

Title of the study:	Alfuzosin in Uretheric Stones (L_9795)		
Investigator(s):	Dr. José Reis Santos British Hospital Rua Tomas da Fonseca 1000 Lisboa		
Study center(s):	1 active site British Hospital Portugal		
Publications (reference):	NA		
Study period: **Date first patient enrolled:** **10-Aug-2006** **Date last patient completed:** **07-Nov-2006**		**Phase of development:** IIIb	
Objectives:	**Primary**: To assess the effect of alfuzosin compared with placebo, for 7 days, on the outcome of patients with uretheric stones submitted to E.S.W/L., namely the percentage of patients without imagiologic evidence of any stone after 72h to 96h. **Secondary**: To assess the effect of Alfuzosin compared with placebo on the outcome of patients with uretheric stones submitted to E.S.W.L., namely in the percentage of patients without imagiologic evidence of any stones after the first 24 hours and at 7th day. To assess the effect of alfuzosin compared with placebo, for 7 days, on the outcome of patients with uretheric stones submitted to E.S.W/L., namely the percentage of patients with clinical evidence of stones clearance after 72h to 96 hours (or at 48h, according with phase 2 design). To evaluate pain (Mankoski Pain Scale) in patients treated with alfuzosin versus those who received placebo, over a period of 7 days, after E.S.W.L.		
Methodology:	Randomized, parallel, double-blind, placebo-controlled study.		
Number of patients:	Planned: 220	Randomized: 5	Treated: 5
Evaluated:	Efficacy: NA	Safety: NA	

Diagnosis and criteria for inclusion:	Patients with imagiologic evidence of uretheric stones, age 18 years or more and that signed the informed consent for study participation.	
Investigational product: Dose: Administration:	Alfuzosin 10 mg OD oral	
Duration of treatment: 7 days		**Duration of observation:** 7 days
Reference therapy: Dose: Administration:	placebo NA oral	
Criteria for evaluation:		
Efficacy:	Percentage of patients without imagiologic evidence of any stones 72h to 96 hours after E.S.W.L. (or at 48h, according to phase 2 design).	
Safety:	Adverse events reported by the patient/subject or noted by the investigator.	
Statistical methods:	Descriptive statistics including means, standard deviations, minimums and maximums, should have been presented for the continuous variables. Percentages, along with 95% confidence intervals, should have been presented for the categorical variables. The primary efficacy variable was the percentage of patients without imagiologic evidence of stones at 72-96 hours (or at 48h, according with phase 2 design). For primary analysis percentages, along with 95% confidence intervals should have been presented for the primary efficacy variable. Difference between groups should be tested using qui-square test or exact-Fisher, depending on the variable distribution.	
Summary:	The statistical analysis was not performed because this study was canceled due to recruitment problems. Although the adverse events list is presented in safety results.	
Efficacy results:	NA	
Safety results:	Pyelonephritis – not related to study drug.	
Date of report:	27-Jul-2007	