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:**	NCT00453908
		Study Code:	L_9397
Generic drug name:	Alfuzosin	**Date:**	17/Aug/2007

Title of the study:	Does Alfuzosin OD vs. Placebo in male Patients Facilitate Spontaneus Voiding During Clean Intermittent Self-Catherisation Following Acute Urinary Retention?		
Investigator(s):	Dr. Niels Harving Department of urology Aalborg hospital North		
Study center(s):	10 centres; Denmark		
Publications (reference):	NA		
Study period: Date first **patient/subject** enrolled: 29-05-2004 *Date of first signed* Date last **patient/subject** completed: 11-01-2006 *Date of last patient last visit*		**Phase of development: III**	
Objectives:	Primary objective: To investigate if 14 days of treatmentwith Alfuzosin compared to Placebo, will increase the number of patients with satisfying spontaneous voiding after acute urinary retention treated with Clean Self-catherisation Secondary objective: To investigate the safety of the medical treatment and Self-catherisation.		
Methodology:	Randomized, Double blind, Placebo controlled Parallel assignment		
Number of patients/subjects:	Planned: 160	Randomized: 24	Treated: 24
Evaluated:	Efficacy/Pharmacodynamics: NA	Safety: 5 SAE in one patient, 2 have possible relation to treatment, 3 have no relation to treatment. Patient did continue on treatment.	Pharmacokinetics: NA
	No efficacy evaluation was performed since the study was terminated early due to slow and difficult inclusion		
Diagnosis and criteria for inclusion:	Males >/ = 50 yearswith acute urinary retention and catherisated Benign hypertrophia of prostate Patient is diagnosed in the emergency room or at acute hospitalization		
Investigational product: Dose: Administration:	Alfuzosin 10mg/ day Oral		
Duration of treatment: 14 days		**Duration of observation:** 14 days	

Reference therapy: Dose: Administration:	Placebo NA Oral
Criteria for evaluation:	
Efficacy: Or Pharmacodynamics:	Urinary flow: Qmax >/= 5ml/s without use of RIK with redual urin < 100 ml Days until RIK stop Urinary volumen Urinary infections
Safety:	Adverse events reported by the patient/subject or noted by the investigator
Pharmacokinetics:	NA
Pharmacokinetic sampling times and bioanalytical methods:	NA
Statistical methods:	No statistical analysis was performed – The study was terminated early due to slow and difficult inclusion
Summary:	No statistical analysis was performed – The study was terminated early due to slow and difficult inclusion
Efficacy results: or Pharmacodynamic results:	NA
Safety results:	5 SAE in one patient, 1 have possible relation to treatment, 4 have no relation to treatment. The one which had possible relation to treatment was described as: “patient being a little unwell with constipation”. “Constipation was treated with Laktulose and patient recovered totally” “Study medication was stopped”.
Pharmacokinetic results:	NA
Date of report:	31-05-2007