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Sponsor/company:	sanofi-aventis	**ClinialTrials.gov Identifier:**	NCT00637715
		Study Code:	L_8758
Generic drug name:	Alfuzosin	**Date:**	04/Apr/2008

Title of the study:	Evaluation of the effect of 10 mg alfuzosin (Alfetim Uno) o. d. in patients presenting lower urinary tract symptoms		
Investigator(s):	Center No.l. : Prof. Dr.György Papp Center No.2. : Prof. Dr. Csaba Tóth Center No.3. : Prof. Dr.László Farkas Center No.4. : Prof. Dr. László Pajor		
Study center(s):	Center No.l. : National Medical Center, Department of Andrology and Urology. H-1135 Budapest, Szabolcs u.33-35. Center No.2. : Debrecen University, Medical and Hygienic Science Center (DEOEC), Department of Urology. H-4032 Debrecen, Nagyerdei Krt. 98. Center No.3. : Pécs University, Medical Faculty (PTÁOK), Department of Urology. H-7621 Pécs, Munkácsy M.u.2. Center No.4. : Szeged County Hospital, Department of Urology. H-6725 Szeged, Kálvária sgt.57		
Publications (reference):	NA		
Study period: Date first patient enrolled: 10-December-2003 Date last patient completed: 15-December-2004		**Phase of development:** phase IV study	
Objectives:	**Aim of the study** 1. collection data on the safety and efficacy of the once daily administration of the 10 mg alfuzosin to patients with lower urinary tract symptoms/complaints rendering possible the presence of benign prostatic hyperplasia, in the course of everyday practice 2. collection data on the possibly occurring changed in sexual functions 3. registration of the occurring side-effects		
Methodology:	self-controlled, multicentric		
Number of patients:	Planned: 60	Randomized: NA	Treated: PP (per protocol) population 45, IT (intention to treat) population: 46
Evaluated:	Efficacy: 45	Safety: 46	Pharmacokinetics: NA
Diagnosis and criteria for inclusion:	• patients presenting lower urinary tract symptoms due to BPH • patient aged more than 40 years • Sexually active • signed informed consent		

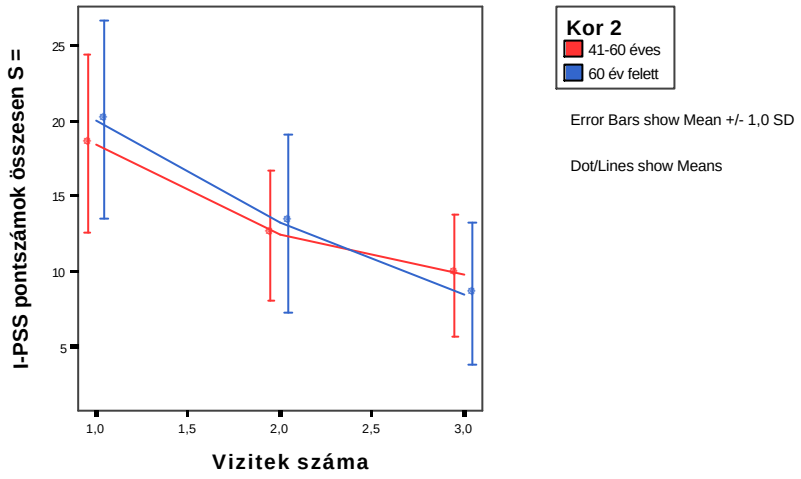
Investigational product:	Alfuzosin
Dose:	l0 mg once daily
Administration:	oral, ingested immediately after the evening meal

Duration of treatment: 6 months	**Duration of observation:** 6 moths

Reference therapy:	NA
Criteria for evaluation:	
Efficacy:	**Primary:** • IPSS /International Prostate Symptom Score/ + quality of life index - based on the data reported by the patient **Secondary:** • DAN-PSS questionnaire related to sexual function - filled in by the patient • Urinary flow parameters, residual urine, change of the prostate volume
Safety:	• spontaneously reported • blood pressure and pulse rate measured in sedentary posture
Statistical methods:	The data of the past history, of the physical examination, of the previous treatments, of the present medical treatments and the adverse events were all evaluated with descriptive statistics. The continuous parameters measured only twice were evaluated with t-probe. Those, which were measured more than twice, were evaluated with repeated variance analyses. The categorical variables were correlated to the basic values with the help of Wilcoxon-probe applying Bonferroni correction. Sub-categories: according to age, two groups were set. These categories (in case of continuous parameters) were integrated as fix variables into the variance analyses. While in case of categorical variables, the sub-groups were compared one by one, considering time parameters - with Mann-Whitney probe.

Summary:

The aim of the study was to collect clinical data in connection with the efficacy and safety of alfuzosin 10 mg once daily in patients having lower urinary tract symptoms suggestive of benign prostate hyperplasia (BPH)
As a secondary endpoint, we aimed to measure functional changes in sexual life, the maximal flow rate, the changes of prostate volume, and other possible side effects.
Study population: 47 eligible, ambulatory patients with lower urinary tract symptoms indicative of BPH were included into the study, the duration of Alfuzosin treatment was 6 months. In two of them (47), it was not possible to finish the treatment (one patient did not take the IP, one had no compliance).
Efficacy: The patients (PP population) showed less symptoms and their condition was improved. The mean IPSS value at baseline and at end-point were 19 4 (Std. error of mean: 0,94) and 9,2 (0,65) respectively. Their complaints decreased significantly, and their life-quality was improved. The mean bother score at baseline and at end-point were 4,6 (0,16) and 1,9 (0,2) respectively. The maximum of urine flow became better significantly The mean urine flow at baseline and at end-point were 12 (0,66) and 15,6 (1,08) respectively.
The sexual function improved , in all the three DAN PSS question groups , the mean total DAN PSS score at baseline and at end-point were 13,3 (2,22) and 6,38 (1,07) respectively.
The data of the tables in the statistical report show that the I-PSS and the weighed QoL values decreased until the last visit. Using the Wilcoxon probe with special attention to a Bonferroni correction, the severity of I-PSS, the sum of score-points of I-PSS, the severity of decrease of QoL compared in each visit showed a significant difference in every cases ($p<0,002$).



Translation:
L-PSS pontszámok összesen S= : summarized L-PSS scores
Vizitek száma: No. of visits
Kor 2: age 2
41-60 éves: age between 41-60 years
60 év felett: age above 60 years

Safety: during the study three adverse events occurred among the 46 patients taking the IP during the 6-months alfuzosin treatment, from which one was serious.

Summary:

Case Summaries[a]

	Adatbeviteli sorszám	Volt nemkívánatos esemény? (Utolsó vizit)	Volt nemkívánatos esemény? (Utolsó vizit)	Nemkívánatos esemény Leírása 1 (Utolsó vizit)	Nemkívánatos esemény Súlyosság 1 (Utolsó vizit)	Nemkívánatos esemény Kapcsolat a gyógyszerrel 1 (Utolsó vizit)
1	19	Igen	Nem Súlyos	Prostatitis chr.	enyhe	nem valószínû
2	31	Igen	SÚLYOS	Vastagbél mûtét	komoly	nem valószínû
3	36	Igen	Nem Súlyos	Lumboischialgia	enyhe	nem valószínû

a. Limited to first 100 cases.

Translation:
Adatbeviteli sorszám: No. of data entry
Volt nemkívánatos esemény (utolsó vizit): Did occurre adverse event ? (closing visit)
Nemkívánatos esemény leírása 1 (utolsó vizit) Narrative of the adverse event 1 (closing visit)
Nemkívánatos esemény Súlyosság 1 (utolsó vizit): Severity of the adverse event
Nemkívánatos esemény Kapcsolat a gyógyszerrel 1 (utolsó vizit): Connection of the adverse event, with the drug judget by the investigator 1 (closing visit)
Igen: yes
Nem Súlyos: not severe
Prostatitis chr: Chronic prostate inflammation
Enyhe: mild
Nem valószínu: not probable
Súlyos: severe
Vastagbél mutét: colon surgery
Komoly: severe
Lumboischialgia: lower back pain

There were no vasodilatory, abnormal ejaculation; erectile dysfunction related adverse event reported in the CRF-s in this study. There was no pt. that discontinued the treatment for AE. The data show that it cannot be connected to the applied treatment. The general clinical safety was evaluated on the basis of side-effects reported at the individual visits. Therefore the patient had to be asked at the visits whether since the last visit he had observed any unusual symptom or had any health problem which he did not have earlier. Cardiovascular safety: It was established at each study, in sedentary posture, after l0 minutes rest on the basis of the measurement of the blood pressure and pulse rate. According to the data we can declare that the applied drug can be used safely, it does not have any influence on blood pressure and pulse rate.

Efficacy results:

Primary: Evaluating the changing of "L score", quality of life, and the changing of I-PSS (International Prostate Symptom Score). 50% of patients were above 60 years old. The patients' data were evaluated on the bases of age as well.

According to data:

- the I-PSS value in the last visit in case of all patients showed significant decline
- number of patients belonging to the severe symptom category fell to its one fourth
- the number of symptoms decreased slower in case of patients over 60 years
- during last visit, the severe problems have disappeared and mild ones increased in age group over 60
- the obstructive and irritative symptom scores changed (decreased) similarly

(Note: In contrast with the including criteria, during the first visit there were only 26 patients in the severe symptom group (56,6%).

According to bother score (representing life-quality):

- the life-quality of patients improved during the visits in significant way
- this significant improvement was noticeable in the severe symptom group as well
- Rate of patients under 60 in the severe symptom group has decreased with higher amount (43%), while in the age group of above 61 this rate was approx. 13%.

Secondary – Evaluation of DAN-PSS questionnaire related to sexual function

Evaluating and analyzing data of 38 patients demonstrates that the sexual function in age group above 60 shows significant improvement during the interim visits. The results of the last visit say that this variable has significantly improved in both groups (under and above 60).

From among data in connection with uresis, we had studied the changes of the urine amount. The evaluation resulted in significant increase (19,6%) of patient who did not have residual urine (not even during the interim visits). This number did not change until the last visit.

The maximum urine flow values showed significant increase (average 2 ml/sec) by the end of study.

The change of prostate volume was not significant.

During the medical treatment the improvement of urination symptoms was noticeable (one third) on the first week, and on 90% of the patients reported at the third – fourth week an improvement.

Statistics

		Maximális flow rate (ml/sec) (1. vizit)	Maximális flow rate (ml/sec) (Idõközi vizit)	Maximális flow rate (ml/sec) (Utolsó vizit)
N	Valid	46	46	46
	Missing	0	0	0
Mean		12,217	14,141	15,728
Median		11,600	13,000	15,250
Std. Deviation		4,4561	5,0823	7,2018
Minimum		5,5	6,2	4,0
Maximum		25,3	28,6	45,7

Translation:
1. vizit : visit No. 1.
Idoközi vizit: Interim control visit
Utolsó vizit: closing visit

Safety results:	According to the results, we can declare that the applied drug can be used for treatment in safe. The applied alfuzosin treatment did not have any influence on blood pressure. During the study three adverse events had occurred from which one was serious. One patient had prostatitis; one patient had lower lumbar pain. The serious adverse event was a hospitalization due to a colon surgery. The evaluation of the data show, that these cannot be connected to the applied treatment. The vital signs parameter evaluation did not show any clinically relevant abnormalities. There were no vasodilatory related, abnormal ejaculation, erectile dysfunction related adverse event reported in the CRF-s in this study.
Date of report:	**28-February-2008**