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

<table>
<thead>
<tr>
<th>Sponsor/company:</th>
<th>sanofi-aventis</th>
<th>ClinicalTrials.gov Identifier:</th>
<th>NCT00453908</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generic drug name:</td>
<td>Alfuzosin</td>
<td>Study Code:</td>
<td>L_9397</td>
</tr>
<tr>
<td>Date:</td>
<td>17/Aug/2007</td>
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<table>
<thead>
<tr>
<th>Title of the study:</th>
<th>Does Alfuzosin OD vs. Placebo in male Patients Facilitate Spontaneous Voiding During Clean Intermittent Self-Catherisation Following Acute Urinary Retention?</th>
</tr>
</thead>
</table>
| Investigator(s): | Dr. Niels Harving  
Department of urology  
Aalborg hospital North |
| Study center(s): | 10 centres; Denmark |
| Publications (reference): | NA |
| Phase of development: | III |

<table>
<thead>
<tr>
<th>Study period:</th>
<th>Date first patient/subject enrolled: 29-05-2004 Date of first signed</th>
<th>Date last patient/subject completed: 11-01-2006 Date of last patient last visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients/subjects:</td>
<td>Planned: 160 Randomized: 24 Treated: 24</td>
<td></td>
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</tbody>
</table>
| Objectives: | Primary objective: To investigate if 14 days of treatment with 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 |
| 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 |
| Diagnosis and criteria for inclusion: | Males ≥ 50 years with acute urinary retention and catherisated Benign hypertrophia of prostate Patient is diagnosed in the emergency room or at acute hospitalization |
| Investigational product: | Alfuzosin  
Dose: 10mg/ day |
<p>| Administration: | Oral |
| Duration of treatment: | 14 days |
| Duration of observation: | 14 days |</p>
<table>
<thead>
<tr>
<th><strong>Reference therapy:</strong></th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dose:</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>Administration:</strong></td>
<td>Oral</td>
</tr>
<tr>
<td><strong>Criteria for evaluation:</strong></td>
<td>Urinary flow: $Q_{\text{max}} \geq 5\text{ml/s}$ without use of RIK with residual urine &lt; 100 ml</td>
</tr>
<tr>
<td></td>
<td>Days until RIK stop</td>
</tr>
<tr>
<td></td>
<td>Urinary volume</td>
</tr>
<tr>
<td></td>
<td>Urinary infections</td>
</tr>
<tr>
<td><strong>Safety:</strong></td>
<td>Adverse events reported by the patient/subject or noted by the investigator</td>
</tr>
<tr>
<td><strong>Pharmacokinetics:</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>Pharmacokinetic sampling times and bioanalytical methods:</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>Statistical methods:</strong></td>
<td>No statistical analysis was performed – The study was terminated early due to slow and difficult inclusion</td>
</tr>
<tr>
<td><strong>Summary:</strong></td>
<td>No statistical analysis was performed – The study was terminated early due to slow and difficult inclusion</td>
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<tr>
<td><strong>Efficacy results:</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>or Pharmacodynamic results:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Safety results:</strong></td>
<td>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: &quot;patient being a little unwell with constipation&quot;. &quot;Constipation was treated with Laktulose and patient recovered totally&quot; &quot;Study medication was stopped&quot;.</td>
</tr>
<tr>
<td><strong>Pharmacokinetic results:</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>Date of report:</strong></td>
<td>31-05-2007</td>
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</tbody>
</table>