Title: Medical Exclusive Therapy for Ureter Stone Using Naftopidil  
ID: SNUBH-URO-2012-03

As Investigator and Responsible Party, Chang Wook Jeong has sole authority to Release this record.

About Responsible Party...
For completed studies: [Record must have a ClinicalTrials.gov ID (NCT number) before results can be entered.]

About Results Data Entry
Delayed Results - Certification or Extension Request, per FDAAA

Responsible Party: Principal Investigator
   Investigator: Chang Wook Jeong [cwjeong]
   Official Title: M.D, Ph.D.
   Affiliation: Seoul National University Hospital

Sponsor: Seoul National University Hospital

Collaborators: Dong-A Pharmaceutical Co., Ltd.

Review Board: Approval Status: Approved   Approval Number: B-1210/175-007
   Board Name: Seoul National University Bundang Hospital Institutional Review Board
   Board Affiliation: Seoul National University Bundang Hospital Institutional Review Board
   Phone: 82-31-787-1376   Email: snubhirb@gmail.com

Data Monitoring Committee? Yes

Oversight Authorities: Korea: Ministry of Food and Drug Safety

Brief Summary: This study is to investigate whether naftopidil is effective or not for the spontaneous passage of ureteral stones with sizes of 3 to 10 mm.

Detailed Description:
   1. Enrollment
      a. patients with ureteral stones of sizes from 3 to 10 mm
      b. patients aged more than 18 years
   2. Randomization
      a. naftopidil 75 mg qd for 14 days or placebo
      b. Standard treatment with pain-killers were also applied (aceclofenac)
   3. Follow-up within 28 days
      a. We confirm the stone free status by CT or X-ray films at 14th and 28th days.
      b. Rates of active treatment will be also evaluated.

Record Verification Date: September 2013

Overall Status: Not yet recruiting

Study Start Date: September 2013
Primary Completion Date: September 2014  [Anticipated]
Study Completion Date: September 2015  [Anticipated]

**Edit**  
**Study Design:**  
- Primary Purpose: Treatment
- Study Phase: Phase 3
- Intervention Model: Parallel Assignment
- Number of Arms: 2
- Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
- Allocation: Randomized
- Endpoint Classification: Safety/Efficacy Study
- Enrollment: 150 [Anticipated]

**Edit**  
**Outcome Measures:**  
**Primary Outcome Measure:**  
- Title: Stone passage rate at 14th day of medication  
- Time Frame: 14th day of medication  
- Description:  
- Safety Issue?: No

**Secondary Outcome Measures:**  
- Title: Stone passage rate at 28th day of medication  
- Time Frame: 28th day of medication  
- Description:  
- Safety Issue?: No

<table>
<thead>
<tr>
<th>Title</th>
<th>Time Frame</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day of stone passage within 4 weeks of medication</td>
<td>at 28th day of medication</td>
<td>We will ask the day of stone passage during medication when we meet the patients at 14th and 28th day of medication.</td>
</tr>
<tr>
<td>amount of analgesics used for 28 days of medication</td>
<td>at 28th day of medication</td>
<td>We will ask the amount of medications when we meet the patients at 14th and 28th day of medication.</td>
</tr>
<tr>
<td>Rate of active treatment</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Safety Issue?: No**
Time Frame: at 28th day of medication
Description: Active treatments include shock-wave lithotripsy or other surgical methods.

Safety Issue?: No

Other Pre-specified Outcome Measures:

Conditions: Urinary Stones
Keywords:

Arms: Placebo Comparator: Control groups with only analgesics
Control groups will receive only analgesics.
Active Comparator: Naftopidil
This interventional group will receive analgesics and naftopidil 75mg po qd.

Interventions: Drug: Naftopidil 75mg po qd
Other Names:
  Flivas(TM) in South Korea

naftopidil 75mg po qd for 28 days with standard analgesic treatment

Eligibility Criteria:
Inclusion Criteria:
  • >= 18 years
  • single 3 to 10 mm ureter stone (longest diameter)

Exclusion Criteria:
  • Presence of multiple ureter stones
  • Renal insufficiency (serum Cr > 1.4)
  • Febrile urinary tract infections
  • pregnancy or breast feeding
  • solitary kidney
  • hypersensitivity to naftopidil
  • current use of any alpha-blocker, calcium-channel blocker, corticosteroid (within 4 weeks)
  • moderate or severe cardiovascular or cerebrovascular disease
  • hepatic dysfunction (>2 x normal)
  • significant active medical illness which in the opinion of the investigator would preclude protocol treatment
Gender: Both
Minimum Age: 18 Years
Maximum Age: 80 Years
Accepts Healthy Volunteers? No

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Email: kmoretry@daum.net

Study Officials/Investigators:
Chang Wook Jeong, M.D., Ph.D.
Study Principal Investigator
Seoul National University Hospital

Locations:
Facility: Seoul National University Bundang Hospital
Seongnam, Kyunggi, Korea, Republic of 463-712
Contact: Sangchul Lee, M.D., Ph.D.
Investigator: Sangchul Lee, M.D.
Role: Principal Investigator
Recruitment Status: Not yet recruiting

Facility: CHA Bundang Medical Center, Bundang hospital
Seongnam, Kyunggi, Korea, Republic of 463-712
Contact: Jong Jin Oh, M.D.
Investigator: Jong Jin Oh, M.D.
Role: Principal Investigator
Recruitment Status: Not yet recruiting

Facility: Seoul National University Boramae Medical Center
Seoul, Korea, Republic of
Contact: Sung Yong Cho, M.D., Ph.D.
Email: kmoretry@daum.net
Investigator: Sung Yong Cho, M.D., Ph.D.
Role: Principal Investigator
Recruitment Status: Not yet recruiting

Facility: Donguk University Ilsan Hospital
Goyang, Kyunggi, Korea, Republic of
Contact: Minchul Cho, M.D., Ph.D.
Investigator: Minchul Cho, M.D., Ph.D.
Role: Principal Investigator
Recruitment Status: Not yet recruiting

Facility: Kangwon National University Hospital
Chuncheon, Korea, Republic of
Contact: Sang Wook Lee, M.D., Ph.D.
Investigator: Sang Wook Lee, M.D., Ph.D.
Role: Principal Investigator
Recruitment Status: Not yet recruiting
Facility: National Medical Center
Seoul, Korea, Republic of
Contact: Woong Na, M.D., Ph.D.
Investigator: Woong Na, M.D., Ph.D.
Role: Principal Investigator
Recruitment Status: Not yet recruiting