Clinical experience of 5-ARI in Taiwan -2009 Final report

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Aims of the Study

- Investigate which parameters correlate with clinical improvement and establish if there is any predictive value of these parameters for response to dutasteride in treatment of clinical BPH
- Evaluate the efficacy and safety of dutasteride in treatment of clinical BPH

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Study population and Methods

- Male patients with age of at least 45 years old in Taiwan with clinical BPH
- Patients who meet all eligible requirements for entry into the study will take dutasteride 0.5mg QD

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Primary endpoints

- Efficacy

  Net change of the International Prostatic Symptom Score (IPSS) and quality of life (QoL) index from baseline to 24 months after the first treatment day
- Safety

  Systemic adverse events

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Secondary endpoints

- Net change of the following parameters from baseline to 24 months after the treatment day

  (1) total prostatic volume (TPV)
  (2) transition zone index (TZI)
  (3) maximum flow rate (Qmax)
  (4) voided volume (Vol)
  (5) postvoid residual volume (PVR)
  (6) prostatic specific antigen (PSA) value

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Inclusion criteria

- Adults with age of 45 years old or above
- Patients with clinical BPH defined as having two of the following items: (1) TPV ≧ 20ml, (2) Qmax ≦ 12ml/s, (3) moderate lower urinary tract symptoms with an IPSS ≧ 8 points
- PSA value < 4 ng/ml, or ≧4 ng/ml but biopsy proven no malignancy
- Free of active urinary tract infection
- Free of acute urinary retention
- Free of neurogenic bladder such as CVA, SCI, or Parkinson's disease with detrusor underactivity

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Exclusion criteria

- Patient's TPV less than 20ml
- History of prostatic cancer
- PSA value ≥ 10 ng/ml without proven free of malignancy
- Chronic stroke, Parkinson's disease or other severe neurological disease with poorly ambulated condition and detrusor underactivity
- Patients with severe cardiopulmonary disease and such as congestive heart failure, arrhythmia, poorly controlled hypertension, not able to receive regular follow-up
- Patients with uncontrolled confirmed diagnosis of acute urinary tract infection
- Patients have laboratory abnormalities at screening including: ALT> 3 x upper limit, AST> 3 x upper limit of normal range
- Patients have abnormal serum creatinine level > 2x upper limit of normal range
- Patients with any contraindication to perform digital rectal examination or transrectal sonography of the prostate (TRSP)
- Patients with any other serious disease considered by the investigator not in the condition to enter the trial

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Study protocol

- Measure all studied parameters at baseline and at 6 months interval after treatment with dutasteride with or without combined with alpha-blocker
- Patients with clinical BPH progression who undergo surgical intervention are included in the final statistics

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Clinical BPH Progression

- (1) IPSS increased by > 4 points
- (2) Qmax decreased by > 2ml/s
- (3) Acute urinary tract or genital tract infection
- (4) PVR increased by 150ml compared with baseline value
- (5) Urinary retention
- (6) Abnormal renal function defined as an elevated creatinine value of > 1.5mg% or increased by 50% of the baseline value
- (7) Hydronephrosis developed
- (8) Urinary incontinence developed

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Study protocol

- All participants' baseline data should be controlled by a central research assistant
- Seasonal report of new participants and new follow-up data should be submitted to the central research assistant for statistic analysis

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Patients enrolled in 2007/2008

- 北部 N=1000
- 中部 N=301
- 南部 N=560
- 東部 N=461
- Total 2322

- Baseline N=2322
- 6M N=1288
- 12M N=844
- 18M N=576
- 24M N=409

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AGE

- Age ranged 45 to 95 years old
- Mean age: 71.2 ± 8.9 years

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