

The Efficacy and Safety of Silodosin Singly or Combined With Ning-mitai Capsules in the Treatment of Benign Prostatic Hyperplasia

NCT05551221

Status	RECRUITING
Phase	Phase 4
Sponsor	Xintian Pharmaceutical
Enrollment	312 participants

Key Eligibility Criteria

Inclusion (6)

- Male Subjects aged 60 ^ 80 years, clinically diagnosed as benign prostatic hyperplasia.
- Has an IPSS score e 8 points at Screening and Baseline.
- Has a 4 d Qmax d 15 ml/s when urination volume > 150 ml.
- Has a prostate volume (PV) e 30 ml by ultrasound examination.
- Subjects who can read, understand, and complete the research questionnaire.

... and 1 more (see full listing online)

Exclusion (13)

- Subjects with prostate cancer or other malignant tumors.
- Subjects have serum tPSA > 10ng/ml, or 4 d tPSA d 10ng/ml while fPSA/tPSA < 0.16 times.
- Subjects suffered from other diseases causing dysuria, such as bladder neck spasm, urethral stricture, neurogenic bladder dysfunction, etc.
- Subjects have suffered from acute urinary retention, or complicated with gross hematuria, urinary tract infection, bladder stones, secondary upper urinary tract hydronephrosis, urinary incontinence, renal insufficiency and other Subjects that researchers believe meet the surgical indications.
- Subjects have undergone prostate surgery, microwave therapy, urethral dilatation or acute urinary retention catheterization or other invasive procedures.

... and 8 more (see full listing online)

Locations (8 total)

Beijing Tiantan Hospital, Capital Medical University, Beijing, Beijing Municipality, China
Beijing Tongren Hospital, Capital Medical University, Beijing, Beijing Municipality, China
The First Affiliated Hospital of Guangzhou Medical University, Guangzhou, Guangdong, China

... and 5 more locations