PLEASE NOTE: *This study has been imported from ClinicalTrials.gov without additional data checks.*

Trial Description

Title

A Randomized, Double-blind, Placebo-controlled, Multi-center, Parallel Group Study to Assess the Efficacy of Vardenafil in the Treatment of Subjects With Symptomatic Benign Prostatic Hyperplasia

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

**Assessment of efficacy of vardenafil in the treatment of subjects with symptomatic Benign
Prostatic Hyperplasia.The purpose of this study is to find out whether vardenafil can
improve the lower urinary tract symptoms of benign prostatic hyperplasia after 8 weeks of
daily administration of 10 mg BID.**

Brief Summary in Scientific Language

[---]*

Organizational Data

- DRKS-ID: **DRKS00004050**
- Date of Registration in DRKS: **2012/07/24**
- Date of Registration in Partner Registry or other Primary Registry: **2008/04/09**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- EudraCT-No.
  (for studies acc. to Drug Law): **2005-002796-32**
- Primary Registry-ID: **NCT00657839 (ClinicalTrials.gov)**
- Sponsor-ID: **11863 (Bayer)**
- Other Secondary-ID: **EudraCT No. 2005-002796-32**

Health condition or Problem studied

- Free text: **Benign Prostatic Hyperplasia**
- ICD10: **N40 - Hyperplasia of prostate**

Interventions/Observational Groups

- Arm 1: **Drug: Levitra (Vardenafil, BAY38-9456)**
- Arm 2: **Drug: Placebo**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, investigator/therapist**
- Control: **Placebo**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **II**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- International Prostate Symptom Score and maximal urinary flow; time frame: 8 weeks

Secondary Outcome

- International Prostate Symptom Score, storing and voiding subscore; time frame: 8 weeks
- IIEF-EF domains score; time frame: 8 weeks
- Safety and tolerability; time frame: 8 weeks

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- **Biberach**
- **München**
- **Rosenheim**
- **Starnberg**
- **Weiden**
- **Hamburg**
- **Hamburg**
- **Marburg**
- **Tostedt**
- **Osnabrück**
- **Düsseldorf**
- **Leverkusen**
- **Mülheim**
- **Leipzig**
- **Kiel**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2005/10/31**
- Target Sample Size: **222**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **[---]***

Inclusion Criteria

- Gender: **Male**
- Minimum Age: **45 Years**
- Maximum Age: **64 Years**

Additional Inclusion Criteria

- Males 45 to 64 years of age

- Lower urinary tract symptoms > 6 months

- International Prostate Symptom Score > 12

Exclusion criteria

- Prostate Specific Antigen > 3 ng/ml

- Residual urine volume > 150 m

- History of myocardial infarction, stroke or life-threatening arrhythmia within the prior 6 months

- Nitrate use

- Other exclusion criteria apply acc. to Summary of Product Characteristics

Addresses

■ **Primary Sponsor**

Bayer

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

■ **Contact for Scientific Queries**

Bayer
Bayer Study Director

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

■ **Contact for Public Queries**

Bayer
Bayer Study Director

Contact for Public Queries

Bayer
Bayer Study Director

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Sources of Monetary or Material Support

- **[---]***

Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2006/06/01**

Trial Publications, Results and other documents

- Further trial documents **Click here and search for drug information provided by the FDA.**
- Further trial documents **Click here and search for information on any recalls, market or product safety alerts by the FDA which might have occurred with this product.**
- Further trial documents **Click here to find results for studies related to Bayer Healthcare products.**
- Further trial documents **Click here to find information about studies related to Bayer Healthcare products conducted in Europe**

Additional Trial Attributes

- *Urological disease:* ***benign prostatic hyperplasia (BPH/BPS)***
- *If other, please specify:* ***[---]****
- *Onset of therapy:* ***[---]****
- *If other, please specify:* ***[---]****

- *If other, please specify:* ***[---]****
- *Study recommendations:* ***[---]****
- *If other, please specify:* ***[---]****
- *German director of clinical investigation:*

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***
- *Further contact:*

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***
- *Function of contact:* ***[---]****
- *Non-interventional study:* ***No***
- *Stage:* ***[---]****

The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.
- Translation on version: 5
- Last processed date by ClinicalTrials.gov: 2016/01/14

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*