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

Trial Description

Title

PERMIXON® 160 mg Hard Capsule Versus Placebo in the Treatment of Symptomatic Lower Urinary Tract Symptoms Due to Benign Prostatic Hyperplasia

Trial Acronym

PERLES

URL of the trial

[---]*

Brief Summary in Lay Language

The aim of this study is to support the efficacy of Permixon 160 mg b.i.d. in treating
subjects with symptomatic Benign Prostatic Hyperplasia (BPH), compared to placebo, using
Tamsulosine LP 0.4 mg as a reference treatment.

Brief Summary in Scientific Language

[---]*

Organizational Data

- DRKS-ID: **DRKS00008796**
- Date of Registration in DRKS: **2015/06/23**
- Date of Registration in Partner Registry or other Primary Registry: **2014/04/18**
- 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): **2014-000222-38**
-

Primary Registry-ID: **NCT02121613 (ClinicalTrials.gov)**

- Sponsor-ID: **P00048 GP 4 04 (Pierre Fabre Medicament)**
- Other Secondary-ID: **2014-000222-38**

Health condition or Problem studied

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

Interventions/Observational Groups

- Arm 1: **Drug: Permixon® 160 mg**
- Arm 2: **Drug: Tamsulosine LP**
- Arm 3: **Drug: Placebo matching Permixon® 160 mg**
- Arm 4: **Drug: Placebo matching Tamsulosine LP**

Characteristics

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

Primary Outcome

- International Prostate Symptom Score (I-PSS score) change; time frame: Day 180; I-PSS score change from baseline to D180

Secondary Outcome

[---]*

Countries of recruitment

- CZ **Czech Republic**
- FR **France**
- DE **Germany**
- IT **Italy**
- ES **Spain**

Locations of Recruitment

- **Berlin**
- **Hagenow**
- **Halle**
- **Hamburg**
- **Herzogenaurach**
- **Hettstedt**
- **Leipzig**
- **Markkleeberg**
- **Michelstadt**
- **Mülheim**
- **Nürnberg**
- **Regensburg**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2014/04/30**
- Target Sample Size: **900**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Male**
- Minimum Age: **45 Years**
- Maximum Age: **85 Years**

Additional Inclusion Criteria

- Male subject

- Between 45 and 85 years old

- Subject with bothersome lower urinary tract symptoms (LUTS) due to BPH such as frequency (daytime or night time), urgency, sensation of incomplete voiding, delayed urination or weak stream

- Subject naive to any prior treatment for LUTS due to BPH

- Prostate enlargement at digital rectal examination (DRE) suggestive of BPH

- I-PSS > 12 at enrolment visit and at inclusion visit

- QoL I-PSS score ≥ 3 evaluated at enrolment visit and at inclusion visit

Exclusion criteria

- Urological history such as urethral stricture disease and/or bladder neck disease, active (at enrolment and/or inclusion or recurrent urinary tract infection, stone in bladder or urethra)

- Any neurologic or psychiatric disease/disorder interfering with detrusor or sphincter muscle

- Insulin-dependent diabetes mellitus and non-controlled non insulin-dependent diabetes mellitus

- Known severe renal insufficiency or creatinine clearance < 30 ml/mn

- Known liver insufficiency or clinically significant abnormal liver function tests

- History of, or concomitant, cardiac arrhythmia or angina pectoris

- Orthostatic hypotension at enrolment or inclusion visit

- Known hypersensitivity to one of the constituents of the study drugs

- Is participating in another clinical trial

Addresses

- **Primary Sponsor**

  Pierre Fabre Medicament

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***
- **Contact for Scientific Queries**

  Pierre Fabre Medicament
  Athmane BOUROUBI, MD

  Telephone: **[---]***
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  URL: **[---]***
- **Contact for Public Queries**

  Pierre Fabre Medicament
  Athmane BOUROUBI, MD

  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 continuing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

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: 3

- Last processed date by ClinicalTrials.gov: 2016/01/14

Please note:
There are additional attributes available concerning this trial. To open an extended view please click here.