# European registry evaluating management practices and pharmacological treatment outcomes in patients with LUTS/BPH. ¡°European LUTS/BPH Registry¡±.

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This is a registry conducted within a sample of European Union (EU) general practitioner (GP) outpatient clinics and urologist¡¯s hospital or office based clinics. The registry aims to collect real-life data across the different countries on: 1....

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|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestopt |
| **Type aandoening** | - |
| **Onderzoekstype** | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON27526

**Bron**
Nationaal Trial Register

**Verkorte titel**
EVOLUTION REGISTRY

**Aandoening**

Lower Urinary Tract Symptoms associated with Benign Prostatic Hyperplasia

### Ondersteuning

**Primaire sponsor:** European Association of Urology Research Foundation (EAU-RF)
**Overige ondersteuning:** GlaxoSmithKline Pharmaceuticals

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

Proportion of patients with symptom persistence (defined as IPSS ¡Ã8 points) at Month 24 in each country.

# Toelichting onderzoek

### Achtergrond van het onderzoek

This is a registry conducted within a sample of European Union (EU) general practitioner (GP) outpatient clinics and urologist¡¯s hospital or office based clinics. The registry aims to collect real-life data across the different countries on i) the usual management of Lower Urinary Tract Symptoms associated with Benign Prostatic Hyperplasia (LUTS/BPH), ii) the effect of LUTS/BPH and its pharmacological treatment outcomes on LUTS/BPH-related health status, general quality of life (QoL), and sexual function.

### Doel van het onderzoek

This is a registry conducted within a sample of European Union (EU) general practitioner (GP) outpatient clinics and urologist¡¯s hospital or office based clinics. The registry aims to collect real-life data across the different countries on:

1. The usual management of Lower Urinary Tract Symptoms associated with Benign Prostatic Hyperplasia (LUTS/BPH);

2. The effect of LUTS/BPH and its pharmacological treatment outcomes on LUTS/BPH-related health status, general quality of life (QoL), and sexual function.

### Onderzoeksopzet

1. FPI planned: DEC 2009;

2. LPI planned: DEC 2010;

3. LPO planned:DEC 2012.

### Onderzoeksproduct en/of interventie

No intervention. Observational.

# Contactpersonen

## Publiek

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## Wetenschappelijk

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

A patient will be considered eligible for inclusion in this registry only if all of the following criteria apply:

1. Males, aged ¡Ã50 years;

2. Patients with LUTS/BPH presenting to the GP or urologist who are either:

A. Presently/recently untreated with pharmacological agents for LUTS/BPH and with an IPSS ¡Ã8 starting LUTS/BPH pharmacological treatment at or directly after the baseline visit, and fulfilling one of the following criteria:

a. Newly diagnosed;

b. Previously managed with watchful waiting;

c. Discontinued LUTS/BPH pharmacological treatment prior to the baseline visit for the following period:

- Blockers or phytotherapy or anticholinergics for ¡Ã 1 month;

- 5ARIs either as monotherapy or in combination for ¡Ã 6 months;

- Other LUTS/BPH medical therapy for ¡Ã1 months;

OR

B. Presently/recently treated with pharmacological agents for LUTS/BPH prior to the baseline visit for the following period, and will continue LUTS/BPH pharmacological treatment:

a. Blockers or phytotherapy or anticholinergics for ¡Ã 1 month;

b. 5ARIs either as monotherapy or in combination for ¡Ã 6 months;

c. Other LUTS/BPH medical therapy for ¡Ã1 months.

3. Patient has given written informed consent to take part in the registry for a period up to 2 years;

4. Patient is capable of understanding and completing the questionnaires.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A patient will not be eligible for inclusion in this registry if any of the following criteria apply:

1. Patients with other pathological or metabolic conditions that might explain the LUTS (e.g. bladder infection, chronic cystitis, bladder/prostate cancer, bladder stones);

2. Patients in whom the decision has been taken at baseline visit to manage them with watchful waiting or other then pharmacological LUTS/BPH therapy;

3. Patients with previous history of prostate cancer;

4. Patients who are participating, or have participated in the last 6 months, in any interventional clinical trial;

5. Patients planning to move to another part of the country or abroad which indicates that they need to discontinue participation prior to the total follow up of 2 years;

6. Patients previously treated with minimal invasive or surgical treatments for their LUTS/BPH or surgical treatments involving the bladder, prostate or urethra;

7. Patients with a history or current illness (including psychiatric) that, in the opinion of the investigator, might confound the results of the registry.

## Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Niet-gerandomiseerd |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestopt |
| (Verwachte) startdatum: | 26-05-2009 |
| Aantal proefpersonen: | 2000 |
| Type: | Werkelijke startdatum |

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 15-09-2009 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL1897 |

| Register | ID |
| --- | --- |
| NTR-old | NTR2013 |
| Ander register | : N/A |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Resultaten

**Samenvatting resultaten**
N/A