# FDC116115: A prospective study of sexual function in sexually active men treated for BPH

Published: 22-08-2012
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Primary: To assess the change in sexual function from baseline to 1 year in sexually active men with at least moderate BPH who are treated with Combodart, compared to placebo.
Secondary: changes in sexual function during 1st 9 months of the study,...

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Prostatic disorders (excl infections and inflammations) |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON44013

**Source**
ToetsingOnline

**Brief title**
FDC116115

### Condition

- Prostatic disorders (excl infections and inflammations)

**Synonym**
benign prostate hyperplasia; prostate enlargement

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** GlaxoSmithKline BV
**Source(s) of monetary or material Support:** GlaxoSmithKline BV

## Intervention

**Keyword:** BPH, dutasteride, sexual dysfunction, tamsulosin

## Outcome measures

### Primary outcome

Change in MSHQ from baseline to month 12.

### Secondary outcome

Changes in MSHQ during 1st 9 months of the study, percentage of subjects reaching various thresholds of change in total MSHQ, changes from baseline in MSHQ and IPSS and Quality of Life score (BII), MSHQ in subpopulations, adverse events.

# Study description

### Background summary

BPH (Benign prostatic hyperplasia) is an independent risk factor for sexual dysfunction and untreated, BPH will generally be associated with worsening sexual function. Treatments for BPH may have beneficial effects on some aspects of sexual dysfunction related to BPH.
Recent expert opinion suggests that sexual function should be assessed in all men with BPH, so clinicians need to understand the likely progression of sexual dysfunction in BPH in order to make informed decisions regarding BPH treatment. Data on the *natural history* of sexual function in BPH is lacking. However both treatments impacting BPH progression and symptomatic treatments have been associated with sexual adverse events in around 10-20% of men treated, especially in the first year of treatment.
There is a consensus of expert opinion that ideally studies of sexual function should include only sexually active men. A placebo control is also considered essential to allow accurate estimation of treatment effects (both positive and adverse), since measurement of all aspects of sexual function is subjective and sexual function may change over time without treatment.
Both alpha blockers and 5-alpha reductase inhibitors (5ARIs) have potentially positive effects on sexual function. The former from direct effect on penile smooth muscle, the latter from reductions in prostate volume and in both drug classes from improvement in lower urinary tract symptoms. Combodart is a

combination of dutasteride (5ARI) and tamsulosin (alpha blocker).
This study will allow reliable assessment of the total impact of BPH treatment with Combodart on sexual function. In addition, the study will examine the impact of treatments on standard BPH efficacy parameters as well as patient global assessments of treatment. This will allow a more detailed evaluation than previously of the balance between treatment benefits and risk of sexual adverse events. In this study all sexual adverse events will be followed up to resolution within the study or at a visit 6 months after cessation of study medication in men with sexual adverse events present at the last visit of the treatment phase.

## Study objective

Primary: To assess the change in sexual function from baseline to 1 year in sexually active men with at least moderate BPH who are treated with Combodart, compared to placebo.
Secondary: changes in sexual function during 1st 9 months of the study, percentage of subjects reaching various thresholds of change in total MSHQ (Men*s Sexual Health Questionnaire), changes from baseline in MSHQ and BPH symptoms, MSHQ in subpopulations, safety and tolerability.

## Study design

Multicenter randomized double blind parallel group phase IV study.
Randomization (1:1) to treatment with:
1. Placebo plus lifestyle advice.
2. Combodart qd plus lifestyle advice.
Treatment duration 1 year.
Approx 476 patients randomized.

## Intervention

Treatment with Combodart or placebo, both combined with lifestyle advice.

## Study burden and risks

Risk: Adverse effects of study medication.
Burden: 8 visits in 1 year. Duration 1-2 h.
Physical examination (incl. internal prostate examination) 3x. Echo prostate and post-void residue 1x.
Blood tests 3x, approx. 40 ml/in total.
Optional blood sample 6 ml for pharmacokinetic sub study.
Questionnaire(s) all visits (IPSS, BII, and patient perception questionnaire).
Life style advice.

# Contacts

**Public**
GlaxoSmithKline BV

Huis ter Heideweg 62
Zeist 3705 LZ
NL
**Scientific**
GlaxoSmithKline BV

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

• Sexually active males aged >=50 years with confirmed clinical diagnosis of BPH.
• IPSS >=12.
• Prostate volume >=30 cc (TRUS).
• PSA >=1.5 ng/mL.
• Men with a female partner of childbearing potential must agree to use effective contraception.

## Exclusion criteria

• Total serum PSA >10.0 ng/mL.
• History or evidence of prostate cancer.

• Current or any prior use of the following prohibited medications (for details see protocol page 19-20):
o a 5α-reductase inhibitor,
o anti-cholinergics within 1 month prior to baseline,
o an alpha-adrenoreceptor blocker within 1 month prior to baseline.
• Any drugs with anti-androgenic properties within the previous 6 months.
• Any drugs noted for gynaecomastia effects, or could affect prostate volume, within 6 months of the Visit 1.
• Current (within 1 month) use of PDE-5 inhibotors for erectile dysfunction, anabolic steroids, drugs know to interact with tamsulosine (e.g. cimetidine, warfarin).
• Use of phytotherapy for BPH within 2 weeks prior to Visit 1.
• Previous prostate surgery.
• Instrumentation of the urethra within 7 days prior to Visit 1 (screening). Catheterisation (<10F) is acceptable with no time restriction.
• History of AUR.
• Post-void residual volume >100 mL

# Study design

## Design

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|---|---|
| Study phase: | 4 |
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |
| Control: | Placebo |
| Primary purpose: | Treatment |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 26-03-2013 |
| Enrollment: | 83 |
| Type: | Actual |

## Medical products/devices used

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|---|---|
| Product type: | Medicine |

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|---|---|
| Brand name: | Duodart |
| Generic name: | dutasteride-tamsulosin |
| Registration: | Yes - NL intended use |

## Ethics review

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|---|---|
| Approved WMO Date: | 22-08-2012 |
| Application type: | First submission |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br>metc-ldd@lumc.nl |

| | |
|---|---|
| Approved WMO Date: | 30-11-2012 |
| Application type: | First submission |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br>metc-ldd@lumc.nl |

| | |
|---|---|
| Approved WMO Date: | 05-12-2012 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br>metc-ldd@lumc.nl |

| | |
|---|---|
| Approved WMO Date: | 20-12-2012 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br>metc-ldd@lumc.nl |

| | |
|---|---|
| Approved WMO Date: | 27-12-2012 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br>metc-ldd@lumc.nl |

Approved WMO
Date: 22-01-2013

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO
Date: 19-04-2013

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO
Date: 16-05-2013

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO
Date: 21-05-2013

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO
Date: 28-05-2013

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO
Date: 10-07-2013

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO

| | |
|---|---|
| Date: | 09-08-2013 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden) |
| | metc-ldd@lumc.nl |

Approved WMO

| | |
|---|---|
| Date: | 23-08-2013 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden) |
| | metc-ldd@lumc.nl |

Approved WMO

| | |
|---|---|
| Date: | 03-02-2014 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden) |
| | metc-ldd@lumc.nl |

Approved WMO

| | |
|---|---|
| Date: | 10-02-2014 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden) |
| | metc-ldd@lumc.nl |

Approved WMO

| | |
|---|---|
| Date: | 14-03-2014 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden) |
| | metc-ldd@lumc.nl |

Approved WMO

| | |
|---|---|
| Date: | 24-03-2014 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden) |
| | metc-ldd@lumc.nl |

Approved WMO

| | |
|---|---|
| Date: | 24-04-2014 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden) |
| | metc-ldd@lumc.nl |

Approved WMO

| | |
|---|---|
| Date: | 28-05-2014 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden) |
| | metc-ldd@lumc.nl |

Approved WMO

| | |
|---|---|
| Date: | 13-02-2015 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden) |
| | metc-ldd@lumc.nl |

Approved WMO

| | |
|---|---|
| Date: | 20-02-2015 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden) |
| | metc-ldd@lumc.nl |

Approved WMO

| | |
|---|---|
| Date: | 28-01-2016 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden) |
| | metc-ldd@lumc.nl |

Approved WMO

| | |
|---|---|
| Date: | 24-02-2016 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden) |
| | metc-ldd@lumc.nl |

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|---|---|
| Approved WMO Date: | 10-03-2016 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>metc-ldd@lumc.nl |

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|---|---|
| Approved WMO Date: | 01-04-2016 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>metc-ldd@lumc.nl |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| Other | EUCTR; EUCTR2012-002047-26-DE |
| EudraCT | EUCTR2012□002047□26-NL |
| CCMO | NL41831.098.12 |