Study FDC114615: Comparative efficacy of DuodartTM plus lifestyle advice versus watchful waiting plus lifestyle advice with step-up therapy to tamsulosin in the management of treatment naÃ¯ve men with moderately symptomatic benign prostatic hyperplasia and prostate enlargement.

Published: 08-10-2010
Last updated: 04-05-2024

Primary: Effectivity. Secundary: Effectivity (questionnaires, progression, surgery), safety and tolerability.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Urinary tract signs and symptoms
Study type	Interventional

Summary

ID

NL-OMON38047

Source
ToetsingOnline

Brief title
CONDUCT

Condition

- Urinary tract signs and symptoms

Synonym

benign prostate hyperplasia, prostate symptoms

Research involving
Human

Sponsors and support

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

Intervention

Keyword: BPH, dutasteride, tamsulosin

Outcome measures

Primary outcome

BPH symptoms.

Secondary outcome

Questionnaires, progression, surgery, adverse effects.

Study description

Background summary

Standard care for men with symptoms of BPH at risk of progression has developed into a cascade that escalates from watchful waiting through single or multiple drugs and finally to surgery if lower urinary tract symptoms are severe or bothersome enough to warrant intervention. The most widely used strategy in urological practice is the system of sequential step-up therapy that forms the essence of standard care. In this system, clinicians and patients decide between them what treatment, if any, shall be initiated. If it is effective and well tolerated it is continued often for long periods. If the therapy is not well tolerated, another can be instituted, or the patient may be referred for surgery. In the case of a failure of efficacy, combination medical therapy can be tried, or the patient referred for surgery. Transurethral resection of the prostate (TURP) is the most commonly used surgical intervention. Although TURP reduces lower urinary tract symptoms (LUTS) to a much greater extent than medical therapy, it is associated with irreversible side effects, most notably urinary incontinence and retrograde ejaculation, and so current practice is typically to utilise medical therapy prior to a surgical referral.

In the only published study on men with LUTS where standard care (watchful waiting followed by escalation) was used, exposure to standard care did not result in an improvement in LUTS compared with baseline at 3, 6 or 12 month evaluation points, although escalation to active therapy only occurred in a minority of subjects. Therefore, it is possible to conclude that standard care when offered to that particular patient population was ineffective in bringing about a measurable improvement in the health status, although those that had intervention had some benefit. This also questions the rationale of *watchful waiting*, especially in men whose baseline parameters, most notably prostate volume, PSA, IPSS and bother scores, place them in a category of being at a heightened risk of disease progression due to worsening of symptoms, acute urinary retention (AUR) or BPH-related surgery.
In men with a symptomatic BPH (moderate to severe symptoms), i.e. a baseline prostate volume of *30 cc and a PSA of *1.5 ng/mL, we now have Level 1b evidence that in long-term therapy, a combination of dutasteride and tamsulosin results in a greater degree of symptom reduction and a lower risk of clinical progression when compared with using either as monotherapy.

Study objective

Primary: Effectivity. Secundary: Effectivity (questionnaires, progression, surgery), safety and tolerability.

Study design

Multicenter randomized open parallel group phase IV study.
Randomisation (1:1) to treatment with:
1. Watchful waiting plus leefadviezen, zo nodig gevolgd door behandeling met tamsulosine.
2. Combodart eenmaal per dag plus leefadviezen.
Treatment duration 2 years.
Approx 760 patients randomized.

Intervention

Watchful waiting or Combodart, both combined with lifestyle advice.

Study burden and risks

Burden: 11 visits in 2 years. Duration 1-2 h.
Physical examination (incl. internal prostate examination) 3x. Echo prostate and post-void residu 1x.
Blood tests 3x approx.. 10 ml/visit. Qustionnaires (IPSS, BII, patient perception questionnaire) all visits.
Lifestyle advice.

Contacts

Public
GlaxoSmithKline

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NL
Scientific
GlaxoSmithKline

Huis ter Heideweg 62
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NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Males aged *50 years with confirmed clinical diagnosis of BPH.
* International Prostate Symptom Score (IPSS) 8*19.
* 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
o a 5*-reductase inhibitor,
o anti-cholinergics,
o an alpha-adrenoreceptor blocker for BPH or LUTS.
* 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.
* 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 within 3 months prior to Visit 1.
* Post-void residual volume >250 mL
* History of postural hypotension, dizziness, vertigo or any other signs and symptoms of orthostasis, which in the opinion of the investigator could be exacerbated by tamsulosin.
* History of breast cancer or clinical breast examination finding of unclear origin or suggestive of malignancy.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-11-2010
Enrollment:	50
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Duodart
Generic name:	dutasteride-tamsulosin
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Omnic
Generic name:	tamsulosin
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	08-10-2010
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	23-11-2010
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	26-11-2010
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	09-12-2010
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

	metc-ldd@lumc.nl
Approved WMO Date:	22-06-2011
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	01-07-2011
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	14-07-2011
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	03-08-2011
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	25-10-2011
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	17-11-2011
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO Date:	24-04-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	10-05-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	31-07-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	22-08-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	12-12-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	11-01-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO Date:	30-08-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	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	clinicaltrials.gov. Registratienummer n.n.b.
EudraCT	EUCTR2010-022111-19-NL
CCMO	NL34029.098.10