A randomized, double blind, parallel group study of vardenafil flexible dose versus placebo in males with erectile dysfunction and their female partners* sexual quality of life. PARTNER II.

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1. Success of maintenance of erection in men with ED.and 2. Improvement of their female partner*s sexual quality of life.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Sexual function and fertility disorders
Study type	Interventional

Summary

ID

NL-OMON29704

Source
ToetsingOnline

Brief title
PARTNER II.

Condition

- Sexual function and fertility disorders

Synonym
impotence

Research involving
Human

Sponsors and support

Primary sponsor: Bayer
Source(s) of monetary or material Support: Bayer B.V.

Intervention

Keyword: BAY 38-9456, erectile dysfunction, partner, sexual quality of life

Outcome measures

Primary outcome

The primary measures of efficacy in this study will be improved success of erection maintenance in men with ED and improvement in female partner*s sexual quality of life after 12 weeks of randomized treatment.

Improvement in erection maintenance will be assessed using the overall post-randomization success rate after 12 weeks of randomized treatment from the Sexual Encounter Profile Question 3 (SEP3) - Did your erection last long enough for you to have successful intercourse? (Yes/No).

Improvement in female partner*s sexual quality of life will be assessed using the change from baseline at LOCF for the quality of life domain from the modified Sexual Life Quality Questionnaire (mSLQQ-QOL) after 12 weeks of randomized treatment. The Sexual Life Quality Questionnaire (SLQQ)17 is a 16-item self-report instrument designed to measure subject and partner*s sexual quality of life (QOL) and treatment satisfaction. For the purpose of the current study, only the 10-item QOL domain will be utilized. Additionally, the SLQQ recall period has been modified for the purposes of the current study to a 4-week recall (mSLQQ), with the author*s permission.

The primary variables will be tested using an ordered hypothesis whereby the

mSLQQ-QOL scores of female partners will only be evaluated following successful analysis of the SEP3 score.

Due to the sequential testing of the two primary variables, both analyses will be tested against a 0.05 level of significance.

Secondary outcome

Secondary efficacy measures for subjects:

• SEP3 at weeks 4, 12, 18, and 24 of treatment compared to placebo.

• Additional Subject Diary questions at weeks 4, 12, 18, and 24, LOCF, and over entire treatment period compared to placebo. Per-subject success rates will be calculated as the number of successes divided by the number of sexual attempts with a response for the question.

• Global confidence question (GCQ) at weeks 12, and 24 of treatment compared to placebo.

• The score for the IIEF questionnaire EF domain (IIEF-EF) at weeks 12 and 24, and LOCF of treatment compared to placebo.

• Scores from the Treatment Satisfaction Scale (TSS) -- Subject Active Medication module at weeks 12, 24, and LOCF of treatment compared to placebo.

• Scores from the mSLQQ-QOL at Week 12, 24, and LOCF of treatment compared to placebo.

• Percentage of subjects achieving back to normal rates of erectile functioning (IIEF-EF > 25) at Week 12, and 24 of treatment compared to placebo.

• Partnership questionnaire (PFB) at week 12, 24 and LOCF of treatment compared to placebo.

Secondary efficacy measures for partners:

• Partner*s scores from the Female Sexual Function Index (FSFI) at Week 24 and

LOCF of treatment compared to placebo.

• Scores from the mSLQQ-QOL for partners at Week 24 of treatment compared to

placebo.

• Scores from the Treatment Satisfaction Scale (TSS) -- Partner Active

Medication module at Week 24 and LOCF of treatment compared to placebo.

• Partnership questionnaire (PFB) at week 12, 24 and LOCF of treatment compared

to placebo.

Study description

Background summary

Erectile dysfunction occurs very often in males and increases with age. More recent studies from the USA and Europe have confirmed that ED is a common disease, with a prevalence ranging from 10% to 52% in the male population.T he causes of ED are varied. Erectile problems may be due to psychological reasons such as depression or stress (psychogenic cause). However the majority of cases presenting for treatment have *organic* causes such as vascular disease, neurological disorders, endocrinological disorders, and anatomical penile problems. In many cases both organic and psychogenic factors are present. In scientific studies, PDE-5 inhibitors, like vardenafil, have proven to be effective. One prospective study designed to measure the impact of ED treatment with vardenafil on female partners has shown a significant effect of treatment of the man*s ED with vardenafil on the sexual quality life of the female partner as well.

Study objective

1. Success of maintenance of erection in men with ED.
and
2. Improvement of their female partner*s sexual quality of life.

Study design

Internationale, multicentrische, prospectieve, gerandomiseerde, dubbelblinde placebo gecontroleerde studie, waarin het effect van vardenafil (in flexibele

doseringen) gedurende 6 maanden op de ED van de man en de seksuele QOL van de vrouwelijke partner zal worden bestudeerd. De studie wordt uitgevoerd bij 308 mannen (en hun vrouwelijke partner).
Studie-opzet:
1. A four week, unmedicated (for ED, including devices), screening period.
2. A four week double-blind treatment period with randomized subject allocation to either 10 mg per dose of vardenafil or placebo.
3. A subsequent 8 week double-blind treatment period during which subjects stay on the assigned treatment of vardenafil or placebo. They will either maintain the previous dosage regimen or will step up to 20 mg or will step down to 5 mg.
4. Two subsequent double-blind treatment periods of 6 weeks each during which subjects stay on either vardenafil or placebo. The previous dosage regimen is either maintained or the previous dose of vardenafil will step up to 20 mg or will step down to 5 mg.
At week 12 a subgroup of subjects/couples will receive an educational program concerning ED, partnership and sex life which lasts until end of randomized treatment.
Total duration of the study: 28 weeks.

Intervention

Treatments to be administered
BAY 38-9456 (Vardenafil) will be supplied as 5 mg, 10 mg, 20 mg and matching placebo tablets.
At Visit 2 (randomization), Week 0, subjects will be randomized to either vardenafil or placebo. All subjects will be dispensed a box containing 2 blister strips of 10 tablets each of Vardenafil 10 mg or placebo for that visit. At Visit 3 (Week 4), Visit 4 (Week 12) and Visit 5 (Week 18) the investigator may, after discussion with the subject, titrate the subject up to 20 mg (or placebo) or down to 5 mg (or placebo) to optimize efficacy or tolerability. At Visit 3 (Week 4), subjects will be dispensed a box of study medication containing 4 blister strips of 10 tablets each of study medication (enough for 8 weeks), either vardenafil or placebo. At Visit 4 (Week 12) and Visit 5 (Week 18) subject will be dispensed a box of study medication containing 3 blister strips of 10 tablets each of study medication (enough for 6 weeks), either vardenafil or placebo and in those sites involved in the education program education material will be dispensed.

Study burden and risks

Burden
Men: Lab samples (2X), brief physical examination (3X), complete physical examination (1X), ECG (2X), questionnaires (IIEF-EF: 4X - GCQ 3X - TSS 3X - mSL QQ QOL 3X) and complete diary after every attempt to have sexual activity.
Women: questionnaires (PFB: 3X - FSFI 4X - TSS 3X - mSLQQ-QOL 3X)
Both men and women: Educational video (1X)

Risks
Possible side effects of Levitra:
Very common: headache, flushing.
Common: dyspepsia, nausea, dizziness, nasal congestion.
Uncommon: photosensitivity reaction, hypertension and hypotension, back pain, myalgia, lacrimation increased visual disturbance (including visual brightness),
skin rash, somnolence, abnormal liver function tests, GGTP increased, blood creatine phosphokinase increased, dyspnea, epistaxis, increased heart rate or pounding heart, face edema.
Rare: syncope, muscle rigidity, intraocular pressure increased, erection increased
(prolonged or painful erections), priapism, allergic reactions, angina pectoris, myocardial ischemia, anxiety, laryngeal edema, partial, sudden, temporary or permanent loss of sight in one or both eyes.

Inschatting belasting en risico
The burden and risks associated with this study are limited.

Contacts

Public
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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patient
-Males with known ED for at least 6 months
-Stable, hetersexual relationship for more than 6 months
-Men, 18-64 years of age
-Documented, dated, written Informed Consent
-Subject and his female partner must make at least four attempts at sexual intercourse on four seperate days during the untreated baseline period
-At least 50% of attempts at sexual intercourse during the baseline period must be unsuccessful, according to one out of three questions from the Subject Diary (see protocol page 15);Partner
-Women, 18 years, and older
-Stable, hetersexual relationship for more than 6 months with the male subject
-Documented, dated, written Informed Consent
-Motivated to support treatment for male partner's ED
-Absence of significant sexual dysfunction as assessed by the total score on the FSFI (Female Sexual Function Index)

Exclusion criteria

Subject
A)Previous or current medical conditions
•Any unstable medical, psychiatric, or substance abuse disorder that in the opinion of the Investigator is likely to affect the subject's ability to complete the study or precludes the subject*s participation in the study.
•Presence of penile anatomical abnormalities (eg penile fibrosis or Peyronie*s disease) which, in the Investigator*s opinion, would significantly impair sexual performance.
•Primary hypoactive sexual desire.
•Spinal cord injury.
•History of surgical prostatectomy (transurethral interventions not excluded).
•Hereditary degenerative retinal disorders such as retinitis pigmentosa.
•Loss of vision of one eye because of NAION.
•Any underlying cardiovascular condition including unstable angina pectoris, that would preclude sexual activity.
•History of myocardial infarction, stroke or life-threatening arrhythmia within the prior 6 months.
•Uncontrolled atrial fibrillation/flutter at screening (ventricular response rate >= 100 bpm).

•Severe chronic or acute liver disease (Child-Pugh B), history of moderate or severe (Child-Pugh C) hepatic impairment.
•Clinically significant chronic haematological disease which may lead to priapism such as sickle cell anemia, multiple myeloma and leukemia.
•Bleeding disorder.
•Significant active peptic ulceration.
•Resting hypotension (a resting systolic blood pressure of < 90 mm Hg) or hypertension (a resting systolic blood pressure > 170 mm Hg or a resting diastolic blood pressure > 110 mm Hg).
•History of malignancy within the past 5 years (other than squamous or basal cell skin cancer).
•History of positive test for Hepatitis B surface antigen (HbsAg) or Hepatitis C.
•Symptomatic postural hypotension within 6 months of Visit 1.
B) Concomitant medication
•Subjects who are taking nitrates or nitric oxide donors.
•Subjects who are taking oral or injectable androgens.
•Subjects who are taking anti-androgens.
•Subjects who are taking the following potent inhibitors of cytochrome P450 3A4: HIV protease inhibitors such as ritonavir or indinavir, the anti-mycotic agents itraconazole and ketoconazole (topical forms are allowed) or erythromycin.
•Subjects who have received any investigational drug (including placebo) within 30 days of Visit 1.
•Use of any treatment for ED within 7 days of Visit 1 or during the study, including oral medications, vacuum devices, constrictive devices, injections or urethral suppositories.
•Subjects who are taking alpha-blockers at Visit 1.
;B)Abnormal laboratory values
•Subjects who have a serum total testosterone level more than 25% below the age-adjusted lower limit of normal according to the range of the testing laboratory.
•Subjects with a serum creatinine clearance (calculated) < 30.0 mL/min.
•Elevation of AST and/or ALT > 3 times the upper limit of normal.;Partner
•Any unstable medical condition or substance abuse disorder that, in the opinion of the Investigator, is likely to affect the partner*s ability to complete the study or precludes the partner*s participation in the study. ;Subject and partner
-Subjects unwilling/ unable to meet protocol requirements
-Subjects with known hypersensitivity to Vardenafil, BAY 38-9456 or any other component of the investigational medication
-Subjects with a history of unresponsiveness to any PDE5 Inhibitor treatment

Study design

Design

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):	19-07-2006
Enrollment:	80
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Levitra
Generic name:	Vardenafil HCl
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	23-05-2006
Application type:	First submission
Review commission:	IRB Amsterdam: Independent Review Board Amsterdam (Amsterdam)
Approved WMO Date:	13-07-2006
Application type:	First submission
Review commission:	IRB Amsterdam: Independent Review Board Amsterdam (Amsterdam)
Approved WMO Date:	11-12-2006
Application type:	Amendment

Review commission:	IRB Amsterdam: Independent Review Board Amsterdam (Amsterdam)
Approved WMO Date:	09-01-2007
Application type:	Amendment
Review commission:	IRB Amsterdam: Independent Review Board Amsterdam (Amsterdam)
Approved WMO Date:	23-01-2007
Application type:	Amendment
Review commission:	IRB Amsterdam: Independent Review Board Amsterdam (Amsterdam)
Approved WMO Date:	26-01-2007
Application type:	Amendment
Review commission:	IRB Amsterdam: Independent Review Board Amsterdam (Amsterdam)

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
EudraCT	EUCTR2006-001228-37-NL
Other	http://www.bayerhealthcare.com
CCMO	NL12473.003.06