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Multicentric prospective study for Therapy of Erectile Dysfunction After nerve sparing radical Prostatectomy: sildenafil (50 mg daily dosing) versus intracorporeal injection of alprostadil (2.5 µg - 10 µg 3/week)

Submission date 01/08/2006	**Recruitment status** Stopped	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 04/12/2006	**Overall study status** Stopped	
Last Edited 18/10/2011	**Condition category** Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2006-003-TEDAP

Study information

Scientific Title

Acronym
TEDAP

Study objectives
Current hypothesis as of 25/01/2008:
The trial objective is to demonstrate a non-inferior efficacy of Sildenafil 50 mg daily dosing (Viagra-Daily-Dosing [VDD] group) compared to intracorporeal injection of Alprostadil 2.5 µg - 10 µg thrice weekly (Intra-Corporeal Injection [ICI] group) as a therapeutic option after bilateral nerve sparing prostatectomy measured by International Index of Erectile Function (IIEF-EF) domain score after 36 weeks of treatment and after 6-weeks of therapy-free interval at week 42 (follow-up one).

Previous hypothesis:
The trial objective is to demonstrate a non-inferior efficacy of sildenafil 50 mg daily dosing (Viagra-Daily-Dosing group) compared to intracorporeal injection of alprostadil 10 µg thrice weekly (Intra-Corporeal Injection group) as a therapeutic option after bilateral nerve sparing prostatectomy measured by International Index of Erectile Function (IIEF-EF) domain score after 36 weeks of treatment and after six-weeks of therapy-free-interval at week 42 (follow-up one).

Please note that as of 25/01/2008 this record was updated to show a difference in the dosage of alprostadil given to the participants. All changes relating to this update are shown in the relevant sections under the date 25/01/2008. Please also note that the title of this trial has changed from: 'Multicentric prospective study for Therapy of Erectile Dysfunction After nerve sparing radical Prostatectomy: sildenafil (50 mg daily dosing) versus intracorporeal injection of alprostadil (10 µg 3/week)' to the above-mentioned title.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Mainz Ethics Committee (Germany) on the 25th January 2008 (ref: 837.258.06 (5356)).

Study design
Prospective, randomised, open-label, multicentre phase IV study with a parallel group design.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Erectile dysfunction

Interventions
Current interventions as of 25/01/2008:
Trial medication:
1. Viagra® (50 mg oral daily dosing)
2. Caverject Impuls® (2.5 µg - 10 µg three times weekly)

Previous interventions:
Trial medication:
1. Viagra® (VDD: Viagra-Daily-Dosing, 50 mg oral daily dosing), and
2. Caverject Impuls® (ICI: Intracorporeal injection, 10 µg three times weekly)

The study was terminated prematurely on 02/11/2010 due to an unexpected high number of drop-outs in the Caverject® group.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Sildenafil and alprostadil

Primary outcome measure
The primary outcome variable is the IIEF-EF domain score (six questions) measured at week 42, after 36 weeks of treatment and a therapy-free interval of six weeks.

Secondary outcome measures
Secondary endpoints are:
1. IIEF-EF domain score (six questions) after week four, 12, 24, 36, and 52.
2. IIEF domain score (15 questions) after week four, 12, 24, 36, 42 and 52.
3. Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) after week four, 12, 24, 36, 42 and 52.
4. Patient satisfaction measured by patient diary during week five, week 13, 25, 37, 42 and 51.
5. Proportion of patients achieving a normal IIEF-EF domain score (more than 25) in week four, 12, 24, 36, 42 and 52.

Overall study start date
01/11/2006

Completion date
01/11/2009

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Signed and dated informed consent indicating that the patient has been informed of all pertinent aspects of the trial before undergoing screening for the study
2. Ability of patient to understand character and individual consequences of clinical trial
3. Men older than 30 and younger than 65
4. Preoperative normal IIEF domain score more than 60 (total: 75)
5. Preoperative normal IIEF-EF domain score more than 25 (total: 30)
6. No neo-adjuvant therapy for prostate cancer before surgery
7. No use of drugs or devices for Erectile Dysfunction (ED) treatment before surgery (e.g. PDE-5-Inhibitor)
8. Patient in stable heterosexual relationship for at least six months
9. Planned surgery techniques: bilateral nerve sparing radical retropubic prostatatectomy
10. No adjuvant therapy after prostatectomy (i.e. androgen deprivation, radiatio therapy)
11. Documented clinical diagnosis of postoperative erectile dysfunction based on IIEF domain score less than 60
12. Documented clinical diagnosis of postoperative erectile dysfunction based on IIEF-EF domain score less than 25

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
It is planned to enroll 194 patients in the trial (Last patient out on 06/10/2010)

Key exclusion criteria
1. Hypotension (Blood Pressure [BP] less than 90/50 mmHg)
2. Hypertension (BP more than 170/110 mmHg)
3. Patients with significant cardiovascular diseases in the last six months, including cardiac failure, myocardial infarction, unstable angina, stroke, symptomatic or clinically significant arrhythmias
4. Patients with blood coagulation disorder
5. Patients who are advised against sexual activity for medical reasons (e.g. patients with severe cardiovasucular disorders)
6. Patients who have conditions that might predispose them to priapism, such as sickle cell anaemia or trait, multiole myeloma, or leukaemia
7. Patients with severe liver insufficiency (e.g. cirrhosis, CHILD C)

8. Patients with severe kidney insufficiency (Creatinin-Clearance less than 30 ml/min)
9. Patients with hereditary degenerative retinal disorders such as Retinitis pigmentosa
10. Patients suffering from loss of vision on one eye due to Non-arteritic Anterior Ischemic Optic Neuropathy (NAION)
11. Patients with anatomical deformation of penis, such as angulation, cavernosal fibrosis or Peyronie´s disease
12. Known hypersensitivity to Sildenafil, Alprostadil or any compound of the trial medication
13. Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption
14. Any of the investigational drugs taken four weeks prior to screening
15. Patients who are currently prescribed, taking and/or likely to be treated with nitrates or nitric oxide donors in any form on either a regular or intermittent basis
16. Patients being treated with alpha blockers for therapy of arterial hypertension
17. Patients who are receiving concomitant treatment with CYP3A4 inhibitor (e.g. ritonavir)
18. Alcohol or drug abuse
19. Participation in any other trial

Date of first enrolment
01/11/2006

Date of final enrolment
01/11/2009

Locations

Countries of recruitment
Germany

Study participating centre
Klinikum Bremen-Mitte gGmbH
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Sponsor information

Organisation
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Sponsor type
University/education

Website
http://www.uni-mainz.de/eng/

ROR
https://ror.org/023b0x485

Funder(s)

Funder type
Industry

Funder Name
Pfizer Pharma GmbH (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration