# 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	Recruitment status Stopped	Prospectively registered	
01/08/2006		∐ Protocol	
Registration date	Overall study status	Statistical analysis plan	
04/12/2006	Stopped	Results	
Last Edited	<b>Condition category</b> Urological and Genital Diseases	Individual participant data	
18/10/2011		<ul><li>Record updated in last year</li></ul>	

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Ludger Franzaring

#### Contact details

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# Additional identifiers

Protocol serial number 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

## Study type(s)

Treatment

#### 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(s)

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.

#### Key secondary outcome(s))

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.

#### 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** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

Male

#### 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 Bremen Germany D-28177

# Sponsor information

#### Organisation

Johannes Gutenberg Universität Mainz (Germany)

#### **ROR**

https://ror.org/023b0x485

# Funder(s)

# Funder type

Industry

#### Funder Name

Pfizer Pharma GmbH (Germany)

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration