

A placebo controlled, flexible dose, randomised controlled trial to assess the efficacy of sildenafil citrate in men with erectile dysfunction after anterior resection for rectal carcinoma

Submission date

15/07/2005

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

10/10/2005

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

13/10/2009

Condition category

Urological and Genital Diseases

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

ED1/2004, Version 2: 25 March 2005

Study information

Scientific Title

Study objectives

Sildenafil after anterior resection for rectal cancer is efficacious in the management of erectile dysfunction.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised placebo controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Erectile dysfunction

Interventions

Sildenafil versus placebo

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Sildenafil citrate

Primary outcome(s)

Erectile dysfunction domain score (sum of questions 1-5 and 15) of the International Index of Erectile Function (IIEF) Questionnaire

Key secondary outcome(s)

1. Responses to the Global Efficacy Assessment Questions (GEAQ)
2. Score of the responses to all the questions of the IIEF Questionnaire
3. Index score of the Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) questionnaire
4. Event Log Variables: Percent of Attempts at Intercourse that were successful, Number of Successful Attempts per Week, Number of Attempts per Week
5. Cessation of treatment due to lack of efficacy or intolerable adverse events
6. Quality of life (EORTC QLQ-C30)
7. Responses to the Sexual Health/Quality of Life supplemental questionnaire (SHQL)

Completion date

20/09/2006

Eligibility

Key inclusion criteria

1. Outpatients aged 18 years or over
2. Resection for tumours of the rectum, and where treatment has been completed
3. Diagnosis of erectile dysfunction (ED) confirmed by a Sexual Health Inventory-Male (SHI-M) score of 21 or less. Erectile dysfunction is defined as 'the inability to achieve and/or maintain an erection of the penis sufficient to permit satisfactory sexual performance' (Impotence National Institutes of Health [NIH] Consensus Conference, JAMA 1993, 270: 83-90).
4. In a stable relationship
5. Written informed consent obtained

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Male

Key exclusion criteria

1. Unwilling or unable (i.e. not in a sexual relationship) to engage in sexual activity during the 12 week treatment period
2. Current prescription for and/or taking nitrates or nitric oxide donors in any form (oral, sublingual, transdermal, inhaled) on either a regular or intermittent basis
3. Current prescription for nicorandil
4. History of intolerance or hypersensitivity to morphine (or to any other opiates) or to any component of the tablet formulations of sildenafil
5. Previously prescribed pharmacological treatment for ED (any other non-pharmacological treatment (e.g. vacuum devices) for ED must be terminated on or before the screening visit and must not be used at any time during the study)
6. Receipt of a new, or a change to existing, medication known to be causally associated with ED such as but not limited to beta-blockers, thiazide diuretics or antidepressants, within the two weeks prior to screening
7. Concomitant treatment, due to requirement of dosage adjustment, with ritonavir, other protease inhibitors, erythromycin, ketoconazole, cimetidine or other CYP3A4 inhibitors
8. Likelihood of requiring treatment during the study period with drugs not permitted by the study protocol
9. Participation in any other studies involving investigational or marketed products, concomitantly or within 30 days prior to entry in the study

10. Genital anatomical deformities that would significantly impair erections (e.g. severe penile fibrosis)
11. Predisposition to priapism
12. Active peptic ulcer
13. Requirement for a 25 mg starting dose of sildenafil, in the opinion of the investigator
14. Significant cardiovascular disease including cardiac failure, myocardial infarction, unstable angina, stroke, symptomatic or clinically significant cardiac arrhythmias in the last six months, uncontrolled hypertension, hypotension or history of postural hypotension, or judged by the investigator to be cardiovascularly unfit for sexual activity
15. Known history of retinitis pigmentosa
16. Any medical (including known history of major haematological, renal or hepatic abnormalities) or psychological condition or social circumstances that may increase risk to themselves or others by participating or would impair their ability to participate reliably in the study (unwilling or unable to complete Event Log worksheets or questionnaires consistently and accurately)
17. Intention to donate blood or blood products during the period of the study

Date of first enrolment

01/10/2005

Date of final enrolment

20/09/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

University Hospital Birmingham NHS Trust

Birmingham

United Kingdom

B15 2TH

Sponsor information

Organisation

University Hospital Birmingham NHS Foundation Trust (UK)

ROR

<https://ror.org/014ja3n03>

Funder(s)

Funder type

Industry

Funder Name

Pfizer Ltd (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2008		Yes	No