ISRCTN86213744 https://doi.org/10.1186/ISRCTN86213744

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	Recruitment status
15/07/2005	No longer recruiting
Registration date	**Overall study status**
10/10/2005	Completed
Last Edited	**Condition category**
13/10/2009	Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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

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

Study design
Randomised placebo controlled trial

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
Sildenafil versus placebo

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Sildenafil citrate

Primary outcome measure

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

Secondary outcome measures
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)

Overall study start date
01/10/2005

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

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
50 subjects per group (100 in total)

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
England

United Kingdom

Study participating centre

University Hospital Birmingham NHS Trust
Birmingham
United Kingdom
B15 2TH

Sponsor information

Organisation
University Hospital Birmingham NHS Foundation Trust (UK)

Sponsor details
Harborne
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United Kingdom
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james.neuberger@uhb.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.uhb.nhs.uk

ROR
https://ror.org/014ja3n03

Funder(s)

Funder type
Industry

Funder Name
Pfizer Ltd (UK)

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

Study outputs

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