The effect of nerve sparing anterior resection on erectile function and the prospect of therapeutic early intervention

Submission date 30/09/2005	Recruitment status No longer recruiting	Prospectively registered
		[_] Protocol
Registration date	Overall study status	[] Statistical analysis plan
30/09/2005	Completed	[_] Results
Last Edited	Condition category	Individual participant data
09/03/2018	Urological and Genital Diseases	[_] Record updated in last year

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

N0264146222

Study information

Scientific Title

The effect of nerve sparing anterior resection on erectile function and the prospect of therapeutic early intervention: a randomised controlled trial

Study objectives

The effect of a combination of nerve sparing resection and therapy with sildenafil on function following anterior resection.

Ethics approval required Old ethics approval format

Ethics approval(s) Not provided at time of registration

Study design Randomised controlled trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Hospital

Study type(s) Treatment

Participant information sheet Not available in web format, please use contact details to request a participant information sheet

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

Interventions Patients undergoing anterior resection to be randomised between sildenafil versus placebo

Intervention Type Drug

Phase Not Applicable Drug/device/biological/vaccine name(s) Sildenafil

Primary outcome measure Not provided at time of registration

Secondary outcome measures Not provided at time of registration

Overall study start date 01/10/1999

Completion date 25/12/2004

Eligibility

Key inclusion criteria Patients with rectal carcinoma

Participant type(s) Patient

Age group Adult

Sex Male

Target number of participants Not provided at time of registration

Key exclusion criteria Does not match inclusion criteria

Date of first enrolment 01/10/1999

Date of final enrolment 25/12/2004

Locations

Countries of recruitment England

United Kingdom

Study participating centre Bristol Royal Infirmary Bristol United Kingdom BS2 8HW

Sponsor information

Organisation Department of Health

Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

Sponsor type

Government

Website http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type Hospital/treatment centre

Funder Name United Bristol Healthcare NHS Trust (UK)

Funder Name NHS R&D Support Funding

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