ISRCTN55599282 https://doi.org/10.1186/ISRCTN55599282

Sling versus sphincter for post prostatectomy incontinence

Submission date	Recruitment status	[_] Prospectively registered
10/09/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/09/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
15/04/2019	Surgery	

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
14690

Study information

Scientific Title
A comparison of the effectiveness of the Advance male sling and AMS 800 artificial urinary sphincter for mild to moderate post prostatectomy incontinence: a single-site, two-arm randomised controlled study

Study objectives
A two-arm randomised comparison of the American Medical System (AMS) Advance male sling and AMS 800 artificial urinary sphincter for patients with mild and moderate post prostatectomy incontinence.

Ethics approval required
Old ethics approval format

Ethics approval(s)
11/0528

Study design
Randomised interventional treatment 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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Generic Health Relevance and Cross Cutting Themes; Subtopic: Generic Health Relevance (all Subtopics); Disease: Surgery

Interventions
Advance Male Sling, Polypropylene mesh, retrourethral transobturator position.
Inserted using two needle passers and through a perineal incision.

Artificial Urinary Sphincter, A mechanical device made of silicon, has three components: cuff, pump and a baloon. Implanted through a perineal incision and inguinal incision.

Follow Up Length: 12 month(s)

Study Entry : Single Randomisation only

Intervention Type

Procedure/Surgery

Phase
Phase II

Primary outcome measure
Difference in 24 hour Pad weight; Timepoint(s): 3 months, 6 months, 12 months after surgery

Secondary outcome measures
Not provided at time of registration

Overall study start date
08/02/2013

Completion date
08/02/2014

Eligibility

Key inclusion criteria
1. Post prostatectomy men at least 6 months after surgery
2. Mild to moderate stress urinary incontinence (mild 50-200 ml 1-2 pads/day; moderate 200-400 ml 3-4 pads/day)
3. Able and willing to participate in the study for its duration
4. Able to comprehend and complete health outcomes questionnaires
5. Able to understand instructions related to study procedures and give written informed consent
6. Target Gender: Male; Upper Age Limit 80 years ; Lower Age Limit 40 years

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
Planned Sample Size: 50; UK Sample Size: 50

Total final enrolment
36

Key exclusion criteria
1. Very mild incontinence (<50 ml/day; not approriate for artificial sphincter)
2. Severe incontinence (>400ml; 5 pads or more; not appropriate for male sling)
3. Previous radiotherapy for prostate cancer
4. Previous surgery for post prostatectomy incontinence or urethral stenosis
5. Urodynamics showing detrusor overactivity or compliance loss deemed a significant

contributor to incontinence, or bladder outflow obstruction
6. Any unstable serious coexisting medical condition(s)) including but not limited to: myocardial infarction, coronary bypass surgery, unstable angina, cardiac arrhythmias, clinically evident congestive heart failure, cerebrovascular accident or uncontrolled diabetes or peptic ulcer disease which is uncontrolled by medical management within 6 months prior to Screening visit; which would preclude them from standard therapies as designated within the study design

Date of first enrolment
08/02/2013

Date of final enrolment
08/02/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
250 Euston Road
London
United Kingdom
NW1 2PG

Sponsor information

Organisation
University College London (UK)

Sponsor details
Gower Street
London
England
United Kingdom
WC1E 6BT

Sponsor type
University/education

Website
http://www.ucl.ac.uk/

ROR

https://ror.org/02jx3x895

Funder(s)

Funder type
Industry

Funder Name
American Medical Systems

Alternative Name(s)
AMS

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

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?
Abstract results	preliminary results presented at the Association of Surgeons in Training (ASiT) meeting	01/04/2014	15/04/2019	No	No