

# Sling versus sphincter for post prostatectomy incontinence

|                                        |                                                   |                                                                                                   |
|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>10/09/2013   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>10/09/2013 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>15/04/2019       | <b>Condition category</b><br>Surgery              | <input type="checkbox"/> 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

**Protocol serial number**  
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

**Primary study design**

Interventional

**Study design**

Randomised interventional treatment trial

**Study type(s)**

Treatment

**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 balloon. 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(s)**

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

**Key secondary outcome(s)**

Not provided at time of registration

**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

## Healthy volunteers allowed

No

## Age group

Adult

## Sex

Male

## Total final enrolment

36

## Key exclusion criteria

1. Very mild incontinence (<50 ml/day; not appropriate 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

United Kingdom

England

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

## Sponsor information

**Organisation**  
University College London (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

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? |
|----------------------------------|-----------------------------------------------------------------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Abstract results</a> | preliminary results presented at the Association of Surgeons in Training (ASiT) meeting | 01/04/2014   | 15/04/2019 | No             | No              |