ISRCTN49212975 https://doi.org/10.1186/ISRCTN49212975

Male synthetic sling versus Artificial urinary Sphincter Trial for men with urodynamic stress incontinence after prostate surgery

Submission date	Recruitment status	[X] Prospectively registered
19/07/2013	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/07/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
02/09/2026	Urological and Genital Diseases	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/trials/a-trial-comparing-devices-help-men-urine-leakage-after-prostate-cancer-surgery-master

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
HTA 11/106/01

Study information

Scientific Title

Male synthetic sling versus Artificial urinary Sphincter Trial for men with urodynamic stress incontinence after prostate surgery: Evaluation by Randomised controlled trial (MASTER)

Acronym
MASTER

Study objectives
The trial will investigate whether a male synthetic sling is non-inferior to implantation of an artificial urinary sphincter (AUS) for men who have urinary incontinence after prostate surgery (for cancer or benign disease).

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/1110601

Ethics approval required
Old ethics approval format

Ethics approval(s)
Currently being reviewed by National Research Ethics Service (NRES) Committee South West - Frenchay

Primary study design
Interventional

Study design
Multicentre randomised controlled non-inferiority trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Adult men with urodynamic stress incontinence after prostate surgery

Interventions
Two surgical operations for male urinary incontinence, a synthetic male sling and an artificial urinary sphincter (AUS) implantation will be evaluated. All adult men who have decided in discussion with their urologist to have surgery for urodynamic stress incontinence (USI) resulting from prostate surgery and who consent to participate will be included in the study. If the treating urologist advises that either of the interventions are suitable for the patient and the man agrees to randomisation, he will be randomised to receive one of the two procedures. The patients who are not eligible for randomisation (if the urologist advises one particular type of surgery and/or the man is not willing to be randomised) will be invited to consent to be followed-up.

All men, whether in the randomised controlled trial or who are being followed-up, will complete questionnaires and 3-day urinary bladder diaries at baseline, 6, 12 and 24 months after surgery. Randomised men only will attend a review appointment with their urologist at 12 months following surgery to evaluate the results of surgery, including a 24 hour pad test.

Intervention Type
Other

Primary outcome(s)
1. Clinical effectiveness of implantation of the male sling compared with AUS in terms of self-reported incontinence at 12 months.
2. Cost effectiveness of a policy of primary implantation of the male sling compared with AUS, measured by incremental cost per quality-adjusted life-year (QALY) at 24 months.

Key secondary outcome(s)
1. Risks of each type of surgery
2. Costs of the benefits and risks of each treatment policy
3. Subsequent NHS services (including repeat surgery) needed for men with persistent or recurrent problems
4. The differential effects of the operations on other outcomes such as quality of life and general health
5. Satisfaction of the men with each procedure

Completion date
01/07/2025

Eligibility

Key inclusion criteria
Adult men who have decided in discussion with their urologist to have surgery for urodynamic stress incontinence (USI) resulting from prostate surgery.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Total final enrolment
480

Key exclusion criteria
1. Men who have had previous male sling or AUS surgery.
2. Men with unresolved bladder neck contracture or urethral stricture after prostate surgery.
3. Men who do not consent to be randomised (these men will be asked to consent to follow up).
4. Men with insufficient manual dexterity to operate AUS device.
5. Men who are unable to give informed consent or complete trial documentation.

Date of first enrolment
29/01/2014

Date of final enrolment

31/12/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Bristol Urological Institute
-
Bristol
England
BS10 5NB

Sponsor information

Organisation
North Bristol NHS Trust (UK)

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC) - NIHR Health Technology Assessment Programme - HTA (UK) ref: 11/106/01

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/06/2021	02/06/2021	Yes	No
Results article	comparison of clinical effectiveness and cost-effectiveness	01/08/2022	17/08/2022	Yes	No
Results article	24-month Outcomes	26/08/2026	02/09/2026	Yes	No
Protocol article	protocol	21/02/2018		Yes	No