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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
17/08/2022	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design
Multicentre randomised controlled non-inferiority 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 to request a patient information sheet

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

Phase
Not Applicable

Primary outcome measure
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.

Secondary outcome measures
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

Overall study start date
01/07/2013

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

Age group

Adult

Sex
Male

Target number of participants
360 randomised men and approximately a further 360 men who are not randomised but who have consented to follow-up.

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
England

United Kingdom

Study participating centre
Bristol Urological Institute
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation
North Bristol NHS Trust (UK)

Sponsor details

Trust Headquarters
Beckspool Road
Frenchay
Bristol
England
United Kingdom
BS16 1JE

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal - a 12-month safety outcome data paper has been submitted to a high impact journal (January 2020), the final report (24-month outcomes) will likely be submitted late 2020/early 2021.

Intention to publish date
01/01/2021

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

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?
Protocol article	protocol	21/02/2018		Yes	No
Results article		01/06/2021	02/06/2021	Yes	No
Results article		01/08/2022	17/08/2022	Yes	No