MENDiP: Measurements of overnight penile temperature to Evaluate Nocturnal erection Detection in patients with absence of erectile functioning after robot-assisted radical Prostatectomy

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Penile and scrotal disorders (excl infections and inflammations)
Study type	Observational non invasive

Summary

ID

NL-OMON51631

Source
ToetsingOnline

Brief title
MENDiP

Condition

- Penile and scrotal disorders (excl infections and inflammations)

Synonym
Erectile dysfunction, erection dysfunction

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Erectile dysfunction, Nocturnal erection, Radical prostatectomy, RigiScan

Outcome measures

Primary outcome

Postoperative measurement:

1. Visual detectability of the presence and absence of nocturnal erections in overnight penile temperature measurements

2. Maximal variation in penile temperature during REM-sleep in case of absence of nocturnal erections

Preoperative measurement:

1. Maximal variation in penile temperature during REM-sleep in case of presence of nocturnal erections in men aged 55 - 70 years

2. Maximal variation in penile temperature during nocturnal erections in men aged 55 - 70 years

Secondary outcome

Demographic data including age, BMI, surgeries, comorbidities (diabetes, hypertension, hyperlipidemia, sicklecell anaemia, atherosclerosis, restless legs syndrome, insomnia, sleep apnea), medication and status of smoking are recorded. This ensures inclusion of the right patient population. Furthermore, patients will be asked to fill in the IIEF-5 questionnaire before and after

surgery, which follows RARP protocol.

Study description

Background summary

Erectile dysfunction (ED) occur at a high frequency and the treatment is dependent on the cause of ED. There are two causes of ED defined: somatic nature or psychological nature. The only available method to differentiate in cause is by determining the presence of nocturnal erections in patients. Every man with normal erectile functioning experiences 2 - 5 nocturnal erections each nigh. Patients with a psychological cause of ED do have nocturnal erections as they occur involuntarily. In case of somatic ED, resulting from for example non-nerve-sparing prostatectomy, nocturnal erections are absent. Currently nocturnal erection detection is performed with the "RigiScan". This device was developed in 1985 and requires an update. Patients experience discomfort due to the systems' large size, the system components are not manufactured anymore, and the system runs on outdated software.

To optimize comfort for these patients, the St. Antonius Ziekenhuis studies the feasibilit of nocturnal erection detection with penile temperature measurement. A skin temperature sensor does not require pressure on the penile skin and is therefore much more patient-friendly. Previous studies have found that the penile temperature increases significantly during erection. Furthermore, it has been found that nocturnal erections can be detected with penile temperature measurements. However, it has not been studied whether penile temperature measurements can also determine the absence of nocturnal erections. This is required before the system can be clinically implemented and used in patients with ED.

Study objective

The objective of the MENDiP-study is to determine the feasibility to detect the absence of nocturnal erections with overnight penile temperature sensors. By including patients undergoing a radical prostatectomy, absence of erectile functioning is ensured, and a comparison can be made with normal erectile functioning prior to surgery. By comparing the results of the temperature sensor with simultaneously recorded RigiScan measurements, insight is gained in how penile temperature measurements can be used for nocturnal erection detection diagnostics. The sleep quality is judged on the simultaneously recorded Fitbit measurements, which will also be used to annotate the sleep stages during the overnight measurements. The preoperative measurements give more insight into the effect of age on the penile temperature during nocturnal erections in test subjects with normal erectile functioning at a higher age

compared to the Feeling Hot studies. The outcomes of this study will be used for the development of a new sensor for nocturnal erection detection in patients with ED.

Study design

The MENDiP study is an observational study with a longitudinal design.

Study burden and risks

The burden for the volunteers consists of two ambulatory overnight measurements. The two appointments for information and material distribution will either take place at the hospital or at an external location and will last approximately 30 minutes. There is no risk associated with participation and usage of the temperature sensors. There is no direct benefit for the healthy volunteers for participating, but the outcomes help improve erectile dysfunction diagnostics.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Preoperative measurement:
* Aged 55 - 70 years
* Prostatecancer patients undergoing a non-/unilateral-nerve-sparing radical prostatectomy (RARP)
* Pre-operative IIEF-5 score > 21

2. Postoperative measurement
* Inclusion criteria of preoperative measurement
* Preoperative penile temperature increase during first nocturnal erection of minimally 0.4 degrees Celsius
* Post-operative IIEF-5 score < 12 with absence of morning erections

Exclusion criteria

* Test subjects who are unwilling to sign informed consent
* Test subjects with erectile dysfunction before RARP (IIEF-5 score of below 22)
* (History of) sickle cell aneamia, atherosclerosis and diabetes type I or II. These conditions might influence penile blood circulation and therefore the accuracy of the study outcomes.
* (History of) REM-sleep behavior disorder or other sleep disorders such as restless legs syndrome, insomnia, and sleep apnea
* Usage of sleeping pills or benzodiazepines.
* Postoperative results will be excluded from the study in case of presence of nocturnal erections according to the RigiScan data.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-02-2023
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	Ohmeda temperature probe
Registration:	No

Ethics review

Approved WMO

Date:	19-12-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT05578157

Register	ID
CCMO	NL82813.100.22