Feeling Hot 2: Evaluating nocturnal erection detection with penile temperature measurements in the search of a modern erectile dysfunction diagnostic tool.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Sexual dysfunctions, disturbances and gender identity disorders
Study type	Observational non invasive

Summary

ID

NL-OMON51838

Source
ToetsingOnline

Brief title
Feeling Hot 2

Condition

- Sexual dysfunctions, disturbances and gender identity disorders
- 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,St. Antonius Ziekenhuis (onderzoeksstichting maastschap urologie)

Intervention

Keyword: Erectile dysfunction, Nocturnal erection, Penile temperature, RigiScan

Outcome measures

Primary outcome

The main endpoint of the Feeling Hot 2 study is to determine the change in penile skin temperature and increased duration of (de)tumescence during nocturnal erections. With these outcomes, the validity of temperature measurements to detect nocturnal erections can be determined.

Secondary outcome

Secondary outcome of the Feeling Hot 2 study combines the results of the Feeling Hot 1 study. It is studied what differences in bodily skin temperature exist between nocturnal erections and visually aroused erections. Furthermore, it is studied whether the reference temperature probe placed on the outer thigh can compensate for the environmental influences of blankets and clothing.

Study description

Background summary

Differentiation in nature of erectile dysfunction (ED) is currently made by nocturnal erection detection with the RigiScan. The RigiScan uses outdated software, measurements are user unfriendly and system components are out of stock. In the search of modernizing erectile dysfunctions diagnostics, the question has arisen whether temperature measurements can function as a tool for nocturnal erection detection. With the absence of a pressure component, the

patient experience should improve. Literature and mathematical modelling studies have shown that the penile temperature increases significantly during erection. However, no studies have used penile skin temperature measurements to detect nocturnal erections. The Feeling Hot 2 study explores the validity of this measurement set-up in the search of modernizing erectile dysfunction diagnostics.

Study objective

The objective of the Feeling Hot 2 study is to determine the change in penile skin temperature during nocturnal erections, which will be detected by the RigiScan. Furthermore, the effect of nocturnal erections on the outer thigh skin temperature is determined.

Study design

The Feeling Hot 2 study is an observational study with a cross-sectional design.

Study burden and risks

The burden for the volunteers will be two visits to the hospital and an overnight measurement at home. Hopsital visits 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 will help improve ED diagnostics.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Healthy volunteer without (a history of) erectile dysfunction
Male
Aged 18 - 29 years

Exclusion criteria

Test subjects who are unwilling to sign informed consent
Test subjects with erectile dysfunction
IIEF-5 score of below 17
(History of) sickle cell aneamia, atherosclerosis and diabetes type I or II.
(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.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-05-2022
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Ohmeda temperature probe
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	22-02-2022
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	NCT05183620
CCMO	NL79969.100.21

Study results

Date completed:	27-07-2022
Actual enrolment:	10