Clinical assessment of women with Persistent Genital Arousal Syndrome (PGAS) by quantitative sensory testing (QST) and cornea confocal microscopy (CCM)

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25394

Source
NTR

Brief title
PGAS

Health condition

PGAS

Sponsors and support

Primary sponsor: LUMC
Source(s) of monetary or material Support: LUMC, SoS fonds

Intervention

Outcome measures

Primary outcome

The primary objective of this study is to study signs of small fiber neuropathy in PGAS patients compared to healthy controls

Secondary outcome

Secondary objectives are:
1. To determine if sensory abnormalities in PGAS patients are isolated to the genital region or show a generalized distribution
2. To assess if PGAS is associated with central sensitization
3. To correlate PGAS symptoms to psychological characteristics
4. To compare psychophysical characteristics between PGAS patients and healthy controls
5. To relate the severity of PGAS symptoms to outcomes in psychophysical evaluation

Study description

Background summary

Persistent genital arousal syndrome (PGAS) is characterized by involuntary genital and clitoral arousal that is unwanted and unrelated to subjective feelings of sexual desire. It is rare but with a major negative impact on affected women’s quality of life. The syndrome is likely due to a neuropathy of the nervus pudendus, but this patient population is hardly ever studied. The current study is designed to explore signs and symptoms in PGAS patients and perform psychophysical sensory testing to better understand neuropathy-related involvement in the PGAS syndrome.

Study objective

This study should therefore be considered an exploratory diagnostic trial with the a priori hypothesis that the PGAS complaints are related to a generalized form of small fiber neuropathy with -due to unknown reasons- the focus of complaints directed at the genital extremity.

Study design

single timepoint

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Adult, >18 years of age
- Able to give written informed consent
In addition, for PGAS patients:
- Diagnosed with PGAS, defined by the following criteria:
i. Involuntary genital and clitoral arousal that persists for an extended period of time (hours, days, months);
ii. The physical genital arousal does not go away following one or more orgasms;
iii. The genital arousal is unrelated to subjective feelings of sexual desire;
iv. The persistent feelings of genital arousal feel intrusive and unwanted; and
v. Feelings of distress.
In addition, for healthy controls:
- Not diagnosed with a pain syndrome
- Reporting an average daily pain score of NRS <2 (numerical rating scale score, range 0-10)
- No overactive bladder symptoms or other complaints of micturition

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
PGAS patients and healthy controls:
- Regular use of opioids (>3 of 7 days per week)
- Diagnosis of a central nervous system disease
- Inability to undergo quantitative sensory testing in the genital region (for whatever reason, as judged by the subject or investigator)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-05-2021
Enrollment:	60
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	27-05-2021
Application type:	First submission

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
NTR-new	NL9496
Other	METC LDD : P21.010

Study results