

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

Gepubliceerd: 27-05-2021 Laatste bijgewerkt: 18-08-2022

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25394

Bron

NTR

Verkorte titel

PGAS

Aandoening

PGAS

Ondersteuning

Primaire sponsor: LUMC

Overige ondersteuning: LUMC, SoS fonds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

single timepoint

Contactpersonen

Publiek

LUMC
Monique van Velzen

0715262301

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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)

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	28-05-2021
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies	
Datum:	27-05-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9496
Ander register	METC LDD : P21.010

Resultaten