Neuromodulation of the Dorsal Genital Nerve in Patiënts with Persistent Genital Arousal Disorder

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The primary aim is to investigate the effect of neuromodulation (via UCon) on the symptoms of patients with PGAD. The hypothesis we want to test is whether neuromodulation of the DGN reduces the severity of symptoms of PGAD.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Peripheral neuropathies
Study type	Interventional

Summary

ID

NL-OMON53294

Source
ToetsingOnline

Brief title
NemoPGAD

Condition

- Peripheral neuropathies
- Sexual function and fertility disorders

Synonym
Persistent Genital Arousal Syndrome; Restless Genital Syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,InnoCon Medical ApS

Intervention

Keyword: Dorsal Genital Nerve, Neuromodulation, Persistent Genital Arousal Disorder

Outcome measures

Primary outcome

Primary outcome measures is the effect of neuromodulation on PGAD symptoms.

Secondary outcome

Secondary outcome measures include session duration, stimulation level and

frequency of neuromodulation; effect of neuromodulation on quality of life and

on mental health; and experiences of using UCon.

Study description

Background summary

UCon is a non-invasive modulator which stimulates the DGN through a patch electrode and can relieve symptoms of overactive bladder and fecal incontinence. A side effect of this neuromodulation is a change in sexual function. It is expected that neuromodulation using UCon will lead to relief of symptoms of PGAD, for which there are few other treatment options. As a result, we hope to create a new effective treatment for patients with PGAD.

Study objective

The primary aim is to investigate the effect of neuromodulation (via UCon) on the symptoms of patients with PGAD. The hypothesis we want to test is whether neuromodulation of the DGN reduces the severity of symptoms of PGAD.

Study design

Pilot intervention study

Intervention

Each subject will be administered daily neuromodulation for a total of three weeks, using UCon.

Study burden and risks

The burden for subjects in the NemoPGAD study consists of 1 additional visit and completion of questionnaires. There are no risks associated with the use of UCon. Subjects unable to operate UCon will be excluded.

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

Patiets diagnosed with PGAD

Exclusion criteria

- Patients < 18 years of age
- Incapacitated subjects
- Subjects unable to operate UCon
- Subjects in whom the anatomy of the genitals precludes proper placement of electrodes

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-04-2023
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	UCon neuromodulator
Registration:	No

Ethics review

Approved WMO

Date:	05-04-2023
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL83877.091.23