The effect of spinal cord stimulation and dorsal root ganglion stimulation on histamine induced itch: an experimental pilot study

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To determine if SCS and/or DRGS is can influence the perception of experimentally induced pruritus.

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49164

Source
ToetsingOnline

Brief title
SCS in itch

Condition

- Other condition
- Peripheral neuropathies

Synonym
experimental pruritus, itch

Health condition

experimentele pruritus

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: DRGS, Itch, Pruritus, SCS

Outcome measures

Primary outcome

Itch intensity will be recorded using a visual analog scale (VAS). Patients*

VAS score will be noted at baseline, after switching off of the

neurostimulator, 15 minutes after application of histamine, and 1, 5, 10, 15

and 30 minutes after the stimulator has been switched on. All measurements will

be noted for both sides, separately.

Secondary outcome

The size of the flare will be measured at all timepoints after application of

histamine. At all timepoints after histamine application, character and

variance of itch perception will be determined, by means of a questionnaire.

All measurements will be noted for both sides, separately.

Study description

Background summary

Electrical neuromodulation therapies such as transcutaneous electrical nerve stimulation (TENS), spinal cord stimulation (SCS) and dorsal root ganglion stimulation (DRGS) have earned their place in the treatment of neuropathic pain and are commonly used as a last resort treatment for neuropathic pain. Though it is known that pain and pruritus are neurologically related phenomena,

electrical neuromodulation is far less used in the treatment of itch. None the less, there is evidence that modes of electrical neuromodulation such as TENS are useful in the treatment of pruritus. To our knowledge, there are no papers published on the effects of SCS and DRGS on the occurrence and intensity of itch. We hypothesize that these modes of neuromodulation are effective forms of treatment for itch.

Study objective

To determine if SCS and/or DRGS is can influence the perception of experimentally induced pruritus.

Study design

This is an experimental pilot-study. We will enroll 12 patients, ideally 6 with an SCS-device and 6 with a DRGS-device. These patients will be carefully selected to meet the following criteria: No pre-existent skin disease, no sensibility disorder, no known allergies or hypersensitivities, availability of an unaffected area in a dermatome corresponding to the location of their device, good responder to their neuromodulation therapy.

Intervention

After switching off the SCS or DRGS, histamine will be applied percutaneously to a healthy area of skin innervated by the neurostimulator, as well as to a healthy area of skin not innervated by the neurostimulator. The resulting itch will be recorded, after which the SCS or DRGS will be switch on again. Subsequently, itch intensity will be measured again after 1, 5, 10, 15 and 30 minutes of stimulation.

Study burden and risks

Participants might temporarily experience an increase in pain, after switching off the SCS or DRGS. Maximum duration hereof is approximately 30 minutes, after which the SCS or DRGS will be turned on again. Due to the nature of the study, participants will temporarily experience localized itch and they will develop two flares, comparable to mosquito bites. Both the itch and the flares will vanish spontaneously within one to two hours, as well as within several minutes after application of a corticosteroid containing dermal cream. The risk of serious or permanent harm or serious adverse events is negligible. Switching on and off the neurostimulator is a well-known and routine act to patients.
There is no benefit in participation, other than aiding the advance of science.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Good effect (>= 50% decrease of pain) of spinal cord stimulation (SCS) or dorsal root ganglion stimulation (DRGS) treatment.
- The area innervated by the SCS or DRGS must extend to a healthy, pain-free, uninterrupted area of skin of at least 10x20cm
- Contralaterally, an equal, uninterrupted, healthy area of skin must be available; this must not be innervated by the stimulator.
- Patient must have no objections against switching off his or her device, for up to one hour.
- Age >=18 years
- No ongoing itch perception

Exclusion criteria

- Generalized skin disorder,
- Systemic disease associated with pruritus,
- Complex regional pain syndrome
- Allergy or hypersensitivity
- Contra-indication for histamine administration, such as mastocytosis
- Use of opioids
- Use of oral antihistamines, corticosteroids or other (immunosuppressive) drugs that might prevent potential participants from developing a flare.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	01-09-2020
Enrollment:	12
Type:	Actual

Medical products/devices used

Generic name:	Spinal Cord Stimulator of Dorsal Root Ganglion Stimulator
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	15-05-2020
Application type:	First submission

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL73015.078.20