Effects of tapentadol on chronic pain and parameters of central sensitization.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20680

Source
Nationaal Trial Register

Brief title
PRINCE

Health condition

Chronic Pain, Central Sensitization, tapentadol, pregabalin;
Chronische Pijn, Centrale Sensitisatie, tapentadol, pregabalin

Sponsors and support

Primary sponsor: University Medical Center Groningen, dept of Anesthesiology
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

Central Sensitzation parameters

- pressure pain threshold (PPT)

- pressure pain tolerance threshold (PTT)

- conditioned pain modulation (CPM)

- size of allodynia

- Wind-up ratio (WUR)

- Central Sensitization Inventory (CSI)

Secondary outcome

- Visual Analog Scale (VAS)

- Pain Disability Index (PDI)

- Pain Catastrophizing Scale (PCS)

- Pain Vigilance and Awareness Questionnaire (PVAQ)

- Adverse effects of the medications

- Dosages of the medication during the treatment period

Study description

Background summary

Chronic pain is a serious debilitating factor for health and welfare with a mean prevalence of 27% in the general European adult population. In most of these conditions a cause for the pain is seldom to be found. It is speculated that central sensitization (CS) is directly involved in the process of chronification and maintenance of chronic pain in many conditions.

For that reason, alleviation of central sensitization should be part of the treatment of patients with chronic pain. This has been demonstrated for pregabalin, but in case of tapentadol it is unknown if and how it interferes with CS. Most relevant to this study is the association of CS with chronic low back pain, chronic pelvic pain, endometriosis, vulvodynia, and dysmenorrhea as well as interstitial cystitis/bladder pain syndrome.

Tapentadol is a new class of opioids with a dual mechanism of function. Tapentadol agonises the mu-opioid receptor (ì-OR) and inhibits the reuptake of noradrenaline in the central nervous system. Its particular efficacy in managing chronic neuropathic pain that is attributed to the latter mechanism. The noradrenergic effect might result in modulating descending pain pathways in the central neural system and thereby reduce or alleviate CS.

Due to the low binding affinity of tapentadol to the ì-OR (with adequate analgesic effects), adverse effects associated with opioid usage such as opioid-induced-hyperalgesia, gastrointestinal complications, dependency and tolerability issues are less likely to occur. The core of this study is to explore the effects of tapentadol on parameters of CS in patients suffering from chronic pain. This has not been previously performed.

Study objective

The main objective is to determine the change in CS parameters upon administration of tapentadol in comparison to pregabalin in patients suffering from chronic pain that has a visceral or deep somatic origin.

Study design

T1: Before start of first treatment

T2: At the end of the first treatment

T3: Before the start of the second treatment

T4: At the end of the second treatment

Intervention

- Tapentadol:

Dose: start dose of 50mg 2x/day, increase by 50mg 2x/day every 3 days until sufficient analgesia is reached with tolerable adverse effects. Max 500 mg/day.

Route: Oral administration

Duration: 8 weeks

- Pregabalin:

Dose: start dose of 75mg 2x/day, increase by 75mg 2x/day every 3 days until sufficient analgesia is reached with tolerable adverse effects. Max 600 mg/day.

Route: Oral administration

Duration: 8 weeks

Contacts

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Eligibility criteria

Inclusion criteria

- Gender: female

- Age of patients (18-65 years old)

- Presence of proven endometriosis or CLBPr

- Signs of central sensitization

- No contraindications for opioids or pregabalin.

- Signed informed consent.

Exclusion criteria

- No or insufficient understanding of Dutch language.

- Incapacity to follow instructions.

- Mental incompetence to provide informed consent.

- CLBP with radiation to both legs.

- Pain in the lower leg or at the deltoid muscle (sites for the QST measurement will be

applied)

- Usage of opioids with more powerful spectre, such as oxycodone, fentanyl, morphine in the two weeks prior to start of the study.

- Previous usage of pregabalin or tapentadol

- Alcohol abuse.

- Pregnancy or woman who wish to be pregnant.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2019
Enrollment:	60
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	23-04-2018
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	NL6981
NTR-old	NTR7170
Other	UMCG Research Register number : 201800294

Study results