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

Gepubliceerd: 23-04-2018 Laatst bijgewerkt: 13-12-2022

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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20680

Bron
NTR

Verkorte titel
PRINCE

Aandoening

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

Ondersteuning

Primaire sponsor: University Medical Center Groningen, dept of Anesthesiology
Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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)

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

- 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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2019
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	23-04-2018
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	NL6981
NTR-old	NTR7170
Ander register	UMCG Research Register number : 201800294

Resultaten