Amitriptyline 10% or ketamine 10% cream in neuropatic pain: a randomised doubleblind, placebo-controlled, cross-over multicenter pilot study

Published: 19-01-2015
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The purpose of this study is to investigate the effect size in order to perform a power calculation for calculating a sample size for a powered RCT

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Therapeutic and nontherapeutic effects (excl toxicity)
Study type	Interventional

Summary

ID

NL-OMON47259

Source
ToetsingOnline

Brief title
Pilot study amitriptyline or ketaminecreme in neuropatic pain.

Condition

- Therapeutic and nontherapeutic effects (excl toxicity)

Synonym
neuropathic pain syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Westfries Gasthuis
Source(s) of monetary or material Support: subsidie wordt aangevraagd

Intervention

Keyword: neuropathic, pain-relievingcream, Pilot-study, randomised

Outcome measures

Primary outcome

Difference between active and placebo cream pain score on Numerical Rating Scale

Secondary outcome

Feasibility of a randomised, doubleblind, placebo-controlled, cross-over study with the folowing questions: effectiveness on the other rating scales, percentage patients responding and will be included after the testing phase; comprehensibility and completeness of questionnaires, percentage drop-outs, side effects, logistics and randomization process, tolerance and safety of the creams

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Study description

Background summary

Neuropathic pain influences qualtiy of live, work, sleep and can lead towards depression. Compliance of oral neuropathic painkillers after one year of therapy is low (45%) probably due to less or low effectiveness and side effects such as drowsiness and lack of concentration. Therefore new therapy strategies to reduce neuropathic pain and negative impact of quality of life and society. Poical analgetics are a interesting field to investigate, mainly due to local influence on damaged nerve. The peripheral effect and if used as prescribed without entering bloodstream as an active component central side effects are

rare.

Study objective

The purpose of this study is to investigate the effect size in order to perform a power calculation for calculating a sample size for a powered RCT

Study design

Randomised, double blinded, placebo controlled cross over multicentre pilot study

2 parts:

- double blinded placebo controlled cross over study with amitriptyline 10% /placebo cream (1 week cream A, 1 week wash out,
1 week cream B)

- double blinded placebo controlled cross over study with ketamine 10% / placebo cream (1 week cream A, 1 week wash out,
1 week cream B)

Intervention

local treatment with either ketamine 10% or amitriptyline 10% cream or placebo

Study burden and risks

Patients need to fill in some study forms (BPI, EQ5DL PGIC and specific cream related questions).
There will be 1 or 2 extra visits for our patients in our pain clinic
Low risk during this study, local skin irritation is mentioned in <1% of active cream users and the risk of hematoma as the result of blood collection

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

- peripheral neuropathic pain (DOT: 130)
- >= 18 years old, competent
- >= 5 and <10 on the Visual Analogue Scale (VAS)
- max. 10% of the bodysurface

Exclusion criteria

- pregnancy or planned pregnancy during study period
- open wounds on the place of the neuropatic pain
- current use of topical analgetic
- presence of other painsyndromes, like the widespread painsyndrome
- presence of serious psychological or psyciatric morbidity
- addiction on intoxicans
- insufficient control of the Dutch language
- use of ketamine and amitriptyline
- known allergy of the studymedication (active substance en additives)

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-02-2017
Enrollment:	80
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	not applicable
Generic name:	amitriptyline
Product type:	Medicine
Brand name:	not applicable
Generic name:	Ketamine

Ethics review

Approved WMO Date:	19-01-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-10-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO Date:	24-02-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-02-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-04-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-11-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-02-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-02-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2014-005656-26-NL
CCMO	NL51748.094.15