

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

Published: 19-01-2015

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

## Summary

### ID

NL-OMON47259

### Source

ToetsingOnline

### Brief title

Pilot study amitriptyline or ketaminecreme in neuropathic 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-relieving cream, 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 following 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

## Study description

### Background summary

Neuropathic pain influences quality of life, 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. Topical analgetics are an 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**

### **Public**

Westfries Gasthuis

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### **Scientific**

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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)
- $\geq 18$  years old, competent
- $\geq 5$  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 neuropathic pain
- current use of topical analgetic
- presence of other painsyndromes, like the widespread painsyndrome
- presence of serious psychological or psychiatric 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

EudraCT

CCMO

### ID

EUCTR2014-005656-26-NL

NL51748.094.15