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

Published: 19-01-2015 Last updated: 15-04-2024

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

1 - Amitriptyline 10% or ketamine 10% cream in neuropatic pain: a randomised doubleb ... 25-05-2025

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 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 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

Public

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Scientific

Westfries Gasthuis

3 - Amitriptyline 10% or ketamine 10% cream in neuropatic pain: a randomised doubleb ... 25-05-2025

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