A comparison between Qutenza and duloxetine for the treatment of painful chemotherapy-induced peripheral neuropathy (QULOX): a pragmatic randomized controlled trial

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The primary objective is to determine whether in patients with CIPN pain, treatment with Qutenza has the same effect as treatment with duloxetine

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Peripheral neuropathies
Study type	Interventional

Summary

ID

NL-OMON53741

Source
ToetsingOnline

Brief title
QULOX study

Condition

- Peripheral neuropathies

Synonym
chemotherapy-induced peripheral neuropathy, CIPN

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Ministerie van OC&W,Grunenthal,industrie

Intervention

Keyword: CIPN, Duloxetine, peripheral neuropathy, Qutenza

Outcome measures

Primary outcome

Pain severity at week 12 after start of treatment as measured by the NRS.

Secondary outcome

1. Interference score (BPI) at week 6 and 12

2. Side effect profile at week 1,2,3,4,5 and 6

3. Quality of life (EQ-5D-5L) at week 6 and 12

4. Patient satisfaction (GPE) at week 1,2,3,4,5,6,8,10 and12

5. Pain score (NRS) at week Pain at 1,2,3,4,5,6, 8 and 10 weeks after the start

of treatment

Study description

Background summary

Painful polyneuropathy occurs in approximately 20-40% of patients after the chemotherapy treatment and has a negative influence on quality of life. Nowadays the American Society of Clinical Oncology (ASCO) recommends duloxetine as treatment for CIPN. (Abdi, 2018, p. 588; Hershman et al., 2014, p. 1953) Duloxetine seems to lead to a significant reduction of neuropathic pain, though the evidence for duloxetine and other pharmacological treatment is very poor. (Abdi, 2018, p. 581) Furthermore adverse effects are registered such as somnolence, insomnia, nausea and vomiting. (Salehifar et al., 2020, p. 250; Song et al., 2020) In addition, the majority of studies are small and use very specific in- and exclusion criteria, resulting in no clinically important differences in outcomes.

Qutenza is another possibility for peripheral neuropathic pain treatment (Blair, 2018, p. 1496; Dahan et al., 2012, p. 51) with promising results among patients with CIPN according to a recent study. (Anand et al., 2019, p. 2042) Qutenza is a patch with 8% capsaicin, which is a selective agonist of a transient receptor potential vanilloid-1 (TRPV-1). Qutenza is already registered for the treatment of peripheral neuropathic pain in adults. Research shows 30% pain reduction in patients with diabetic polyneuropathy, HIV induced polyneuropathy and post-herpetic neuralgia after using Qutenza versus 20% in patients receiving a placebo. (Blair, 2018, p. 1498) Skin biopsies of patients with CIPN showed a decrease of intra-epidermal and sub-epidermal nerve fibers. (Anand et al., 2019, p. 2042) Treatment with a Qutenza patch possibly leads to increase or even normalization of intra- and sub-epidermal nerve fibers, epidermal levels of Nerve Growth Factor, Neurotrophin-3 and Langerhans cells. Also, no systemic side effects were found when using Qutenza patches. (Anand et al., 2019, p. 2042).
To our knowledge, no previous randomized study examineds Qutenza in patients with CIPN, and no study compared Qutenza to duloxetine.

Study objective

The primary objective is to determine whether in patients with CIPN pain, treatment with Qutenza has the same effect as treatment with duloxetine

Study design

a pragmatic randomized strategy controlled trial

Intervention

The affected extremity or extremities will be treated with Qutenza (179mg) according to normal procedures of the hospital and as recommended by the manufacturer.
Patients randomized to duloxetine will start with duloxetine 30 mg per day. After 1 week the dose of duloxetine will be increased, if tolerated, to 60 mg per day or more. According to the expertise of the treating specialist the duloxetine may be increased further to reach a desirable effect.

Study burden and risks

The risk is negligible. Qutenza and duloxetine are licensed drugs and are both used for the treatment of CIPN. The study compares the effect of both drugs. The extend of the burden is small. At 10 times (week 0, 1,2,3,4,5 6, 8, 10 eand 12) the patients have to complete several questionnaires, which takes an estimated 15 minutes.

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

- Age >= 18 years of age
- Presence of CIPN grade 1 or higher according to the NCIC-CTC
- Treatment with chemotherapy in the last 5 years
- Able to give oral and written informed consent
- Painful neuropathy with mean pain (1 week) score of >= 4

Exclusion criteria

- Peripheral neuropathy from other causes (e.g. carpal/tarsal tunnel syndrome, radiculopathy,
spinal stenosis, brachial plexopathy)

- Leptomeningeal carcinomatosis
- Use of selective serotonin reuptake inhibitors, exchanging for medication without interaction is
possible following expertise of the pain specialist anti-depressant medication
- Psychiatric disorders which can interfere with cooperation
- Abnormal renal (< GFR 30) or liver function tests (> 2 times normal value)
- Severe heart failure as determined by the cardiologist
- Allergy for duloxetine or capsaicin
- Skin diseases in hands and/or feet, damaged skin
- The presence of uncontrolled/untreated hypertension
- Concomitant use of medication that may interact with duloxetine such as fluvoxamine, ciprofloxacin and enoxacin which is not replaceable and according to the treating specialist not safe to combine with duloxetine
- Any condition that by the judgement of the investigator might interfere with the investigation
- Previous treatment with Qutenza or duloxetine for CIPN

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-10-2022
Enrollment:	103
Type:	Actual

Ethics review

Approved WMO Date:	13-07-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-04-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-02-2024
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
CCMO	NL79669.029.21