A multicenter, Single arm, Open label study of The Repeated Administration Of Qutenza For The Treatment Of Peripheral Neuropathic Pain.

Published: 13-08-2010
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The purpose of the study is to assess the safety and efficacy of repeated treatments of QUTENZA in subjects with peripheral neuropathic pain.

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

Summary

ID

NL-OMON34497

Source
ToetsingOnline

Brief title
STRIDE

Condition

- Peripheral neuropathies

Synonym
pain that is caused by damage to the peripheral nerves, Peripheral Neuropathic Pain

Research involving
Human

Sponsors and support

Primary sponsor: Astellas Pharma B.V.
Source(s) of monetary or material Support: Industrie (Astellas Pharma Europe)

Intervention

Keyword: * Efficacy and safety, * Peripheral Neuropathic Pain, * Qutenza, * Repeated Administration

Outcome measures

Primary outcome

Safety:

- Adverse events (AEs).

- Serious adverse events (SAE's).

- Treatment-emergent adverse events.

- The proportion of subjects who prematurely terminate from the study due to an AE.

- Sensory function: change from screening visit of warm, cold, sharp and vibration sensations and allodynia.

Secondary outcome

Safety:

- Use of concomitant pain medications following each patch application.

- Vital signs.

- The number and percentage of patients with each dermal assessment score at the different visits.

- The proportion of subjects completing at least 90% of the intended patch application duration.

- Neurological assessment.

Efficacy:

- Questionnaires.

- Change in use of concomitant pain medications during the study.

Study description

Background summary

Between 1.5 and 7.7 percent of people are believed to be affected by neuropathic pain in the United States and European countries and the prevalence is rising. Neuropathic pain may last many years and can even be permanent. Due to limited efficacy of existing therapies, neuropathic pain can have a devastating impact on subjects* quality of life and a high societal cost

The treatment of peripheral neuropathic pain syndromes commonly requires the use of multiple medications. However, the use of many of these treatments is often limited by poor tolerability, the need for titration, drug-drug interactions and administration of multiple daily doses. In addition, many patients continue to experience significant pain while taking these treatments.

QUTENZA is developed to give a constant pain relieve at the source of the PNP. The active ingredient in Qutenza, capsaicin (found in chilli peppers), is a highly selective agonist of the transient receptor potential vanilloid 1 receptor (TRPV1). This means that the TRPV1-receptors which are situated in the nociceptors (pain-receptors) in the skin will be activated. Qutenza has a high dose of capsaicin which is released quickly and will cause an overstimulation of the TRPV1-receptors.
Overstimulation will defunctionalize the sensory axons which results in inhibition of pain transmission.

Prolonged pain reduction following QUTENZA application was observed in patients with peripheral neuropathic pain in previous studies.

Study objective

The purpose of the study is to assess the safety and efficacy of repeated treatments of QUTENZA in subjects with peripheral neuropathic pain.

Study design

A multicenter, Single arm, Open label study. Phase IV.

Intervention

The subjects will be entered into the study for approximately 14 months. The subjects will have a maximum of 8 visits during the study.
All subjects will receive Qutenza.

The visits are scheduled as follow:

- The first visit is done to determine whether the subject can be included into the study or not.
- Qutenza patch application visits (intervals of 12 weeks).
- Week 26 visit (visit for all subjects who have not returned to the clinic for a new patch application by that time).
- Termination visit (not earlier than 9 weeks after the last patch application and no later than 65 weeks after the first patch application).
- Unscheduled visits.

Study burden and risks

The following assessments will be done during the visits:

- Physical Exam (all visits, except for patch application visits)
- Neurological Examination (all visits)
- Dermal Assessment of Painful Area by research physician or - nurse (all visits)
- Identification of Painful Area(s) (all visits)
- Pregnancy test for women of child bearing potential (first visit and first patch application visit)
- Vital signs such as bloodpressure and pulse (all visits and measured by the investigator)
- ECG (first visit and - if clinically indicated also at others visits)
- Questionnaires (all visits except unscheduled visits, also in between visits by an automatic telephone system)
- Telephone contacts between visits with a member of the site study team.

In addition to the above a blood sample for routine safety analysis will be taken at visit 1.

The adverse reactions of the study medication could cause a risk for the subjects during the study.

Adverse reactions Qutenza patches: Qutenza is applied on the skin therefore; most adverse reactions are related to the area(s) where the patch/patches is/are applied. Earlier reported adverse reactions are warmth, stinging, burning sensation, pain and redness (erythema) at area where patch is applied.

Some subjects experienced transient increases in blood pressure after patch application.

Adverse reactions topical anaesthetics: skin irritation, redness, itching, rash and oedema at the site of treatment.

Adverse reactions cleansing gel: local skin reactions (e.g. contact dermatitis) or irritation of the eyes and mucous membranes.

Besides these above-mentioned risks, unexpected or unknown risks or adverse reactions could occur.

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

To be included in the clinical trial, subjects must meet all of the inclusion criteria:
1. Male or female between 18 and 90 years of age, inclusive.
2. Be in good health as determined by the investigator.
3. Average pain score >=4 during screening period (using the average reported pain from the Brief Pain Inventory [BPI]).
4. Intact, non-irritated, dry skin over the painful area(s) to be treated.
5. All females of child bearing potential must be willing to use effective methods of birth control during the study and for 30 days following study termination.
6. Be willing and able to comply with protocol requirements for the duration of study participation.
7. Subject has given written informed consent.;Population-specific Inclusion Criteria:
All subjects must meet one (and only one) of the Population-Specific Inclusion Criteria for PHN, HIV-AN, PNI or ISNN or have adequately characterized PNP based on clinical history and examination.;Postherpetic Neuralgia (PHN)
Prior diagnosis of PHN with pain persisting at least 3 months since shingles vesicle crusting, documented by the primary treating physician or investigator.;Or;Painful HIV-Associated Neuropathy (HIV-AN)
Presence of HIV-AN existing for a minimum of 3 months, confirmed using the Brief Peripheral Neuropathy Screen (BPNS) at the time of study entry.;Or;Peripheral Neuropathic Injury (PNI)
Diagnosis of Post-traumatic Peripheral Neuropathic Pain syndrome, including post-surgical neuropathic pain, neuropathic pain due to peripheral nerve injury, confirmed by a qualified pain specialist and persisting for a minimum of 3 months following the traumatic event.;Or Idiopathic Small Nerve Neuropathy (ISNN)
Diagnosis of ISNN based on clinical criteria, (e.g. quantitative sensory testing) or skin biopsy: Neuropathy exclusively or predominantly affecting A-δ (small myelinated) and nociceptive C (unmyelinated) nerve fibres.
Loss of pinprick and temperature sensation in feet.;Or;Other Peripheral Neuropathic Pain (PNP)
Adequately characterized PNP based on clinical history and examination existing at the time of screening.

Exclusion criteria

Subjects will be excluded from the clinical trial if they meet any of the following exclusion Criteria:
1. Any prior receipt of QUTENZA open label or blinded study patches.
2. Use of oral or transdermal opioids exceeding a total daily dose of morphine of 80 mg/day, or equivalent; or any parenteral opioids, regardless of dose, within 7 days preceding the first patch application visit.
3. Lack of an effective pain medication strategy for the subject, such as unwillingness to use opioid analgesics during study treatment, or high tolerance to opioids precluding the ability to relieve treatment-associated discomfort with oxicodone or other analgesic, as judged by

the investigator.
4. Active substance abuse or history of chronic substance abuse within 1 year prior to enrolment or any prior chronic substance abuse (including alcoholism) likely to re-occur during the study period as judged by the investigator.
5. Use of any topical pain medication, such as non-steroidal anti-inflammatory drugs, menthol, methyl salicylate, local anaesthetics, steroids or capsaicin products on the painful areas within 7 days preceding the first patch application visit.
6. Current use of any investigational agent (excluding antiretrovirals in Phase 3 evaluation to treat HIV infection).
7. Unstable or poorly controlled hypertension or a recent history of a cardiovascular event which, in the opinion of the investigator, would put the patient at risk of adverse cardiovascular reactions related to the patch application procedure.
8. Evidence of another contributing cause for peripheral neuropathy, and/or treatment within 90 days prior to screening visit with any drug that may have contributed to the sensory neuropathy.
9. Past or current history of Type I or Type II diabetes mellitus.
10. Current psychotic disorders.
11. Clinically significant abnormal ECG at screening.
12. Hypersensitivity to capsaicin (i.e., chilli peppers or Over-the-counter [OTC] capsaicin products), any QUTENZA excipients, local anaesthetics, oxycodone, hydrocodone, or adhesives.
13. Significant ongoing abnormalities in cardiac, renal, hepatic, or pulmonary function that may interfere either with the ability to complete the study or the evaluation of adverse events.
14. Significant pain of an aetiology other than painful HIV-AN, PHN, PNI, ISNN or other adequately characterized PNP, for example; compression-related neuropathies (e.g., spinal stenosis), fibromyalgia or arthritis.
15. Posttraumatic neuropathic pain due to Complex Regional Pain Syndrome (CRPS, Type I).
16. Active malignancy or history of malignancy during the past 5 years (a history of squamous cell carcinoma or a basal cell carcinoma not involving the area to be treated is allowed).
17. Evidence of cognitive impairment including dementia that may interfere with subject*s ability to complete study evaluations and recall pain levels in the past 24 hours.
18. Planned elective surgery during the trial.
19. Neuropathic pain areas located only on the face, above the hairline of the scalp, and/or in proximity to mucous membranes.
20. Female subjects of child-bearing potential with a positive serum or urine pregnancy test prior to treatment.

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-02-2011
Enrollment:	12
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Qutenza
Generic name:	Capsaicin
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	13-08-2010
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

Approved WMO

Date:	09-11-2010
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

Approved WMO

Date:	17-04-2012
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

Approved WMO

Date:	07-05-2012
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	10-07-2013
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	11-07-2013
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

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	EUCTR2009-016457-18-NL
CCMO	NL32597.075.10